IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO: ETHICON WAVE 5 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.

Dr. Elliott has been the target of multiple *Daubert* motions over the past three years. In that time, his opinions have largely remained the same. In fact, his reports in these Wave cases have not materially changed. In Wave 1, Ethicon challenged all of his opinions and the Court ruled on those challenges. (Doc. No. 2666). In Wave 2 Ethicon adopted its Wave 1 challenges and the Court adopted its earlier rulings. (Doc. No. 3528). For Wave 3, Ethicon decided it was unhappy with the Court's earlier rulings and it levied another scattershot attack on most of Dr. Elliott's opinions. The Court rejected Ethicon's attempt to get a second bite at the apple and adopted its earlier Order reserving for trial any new or newly nuanced attacks. (Doc. No. 4152). Now, Ethicon has decided it is still unhappy with the Court's rulings and is trying to get a third bite at the apple. Notably, Ethicon does not argue that Dr. Elliott materially modified his report or his opinions -- he did not. Ethicon does not argue there is some new testimony undermining Dr. Elliott's opinions – there is not. Ethicon just wants another bite. The Court should summarily deny Ethicon's Motion seeking to revisit issues the parties have fully briefed and this Court has already decided. The Court should adopt its earlier rulings in Wave 1 and Wave 3 and move these cases toward trial.

BACKGROUND

The Court is well acquainted with Dr. Elliott's *bona fides*. Dr. Daniel S. Elliott is an associate professor of urology in the section of Female Urology and Reconstructive Surgery at the Mayo Clinic Graduate School of Medicine in Rochester, Minnesota. He has treated hundreds of patients with mesh-related complications. For over 15 years, he has specialized in treating urinary incontinence in women. He has delivered numerous lectures on treatment options for stress urinary incontinence (SUI) in women, including the limitations of each. He is an editor or reviewer for 15 urologic and gynecologic journals and has reviewed all readily available medical literature on SUI treatment options. He has also reviewed an extensive number of internal Ethicon documents and depositions of its personnel in developing his opinions in these cases.

Dr. Elliott has extensive experience implanting both naturally made and synthetic slings to treat SUI, including polypropylene slings. In fact, synthetic slings were his primary treatment for SUI prior to August, 2013. He implanted several hundred synthetic slings during that time period.

ARGUMENT

I. Ethicon Is Simply Regurgitating Its Previous Attacks on Dr. Elliott (as it did in Wave 3) and the Court Should Deny Ethicon's Motion and Adopt Its Earlier Rulings.

This Court has expressly informed the parties that it does not desire *Daubert* do-overs and that such motions waste the Court's and parties' time. In its Wave 3 *Daubert* Order concerning Dr. Elliott, the Court simply adopted its prior Wave 1 ruling noting "the court will refrain from engaging in the extremely inefficient practice of continuously reexamining qualifications, reliability, and relevance of dozens of experts and their numerous opinions." (Doc. 4152 at 2).

Here, Ethicon's Wave 5 *Daubert* Motion is essentially a wholesale regurgitation of its Wave 1 and Wave 3 motions. In fact, large portions of the Motion are a word-for-word recitation

of Ethicon's Wave 1 and Wave 3 motions. In instances where the present Motion differs from earlier briefs, the "new" issues raised are either wholly irrelevant or are being raised for the first time after years of litigation.

Notably, Ethicon does not allege that Dr. Elliott has materially changed any of his opinions – he has not – nor that there is any new testimony from Dr. Elliott undermining this Court's previous rulings – there is not. Instead, Ethicon largely seeks to have the Court reconsider its earlier rulings with which it disagrees or to attack whole new portions of Dr. Elliott's opinions despite the fact that these opinions have not materially changed for years.

On August 26, 2016, this Court issued its Wave 1 Memorandum Opinion and Order on *Daubert* Motion re: Daniel Elliott, M.D. In this Order, the Court thoroughly assessed Dr. Elliott's qualifications and the reliability and relevance of the opinions he sought to offer. The Court determined that Dr. Elliott could offer some opinions, could not offer others, and, that certain decisions were best reserved for determination at the time of trial. (Doc. No. 2666).

For Wave 2 cases, the parties adopted their Wave 1 briefing and the Court simply adopted its Wave 1 Order. (Dkt. 3528). This reflected the Court's desired approach when dealing with the same expert who had issued a similar report in earlier Waves.

In Wave 3, apparently becoming dissatisfied with the Court's Wave 1 ruling, Ethicon filed a new *Daubert* challenge against Dr. Elliott. On July 20, 2017, this Court issued an Order regarding Dr. Elliott's opinions in Wave 3. (Doc. No. 4152). The Court noted that "the expert opinions proffered [by Dr. Elliott] in Wave 1 are in almost every respect identical to those proffered here [in Wave 3]." *Id.* Recognizing that "these refreshed *Daubert* challenges are different from previous arguments by only the very slightest of degrees," the Court adopted its earlier Wave 1 Order on all previously determined issues and reserved ruling on any new issues

holding that "the trial judge may easily resolve these issues at trial without the need for further briefing or evidentiary hearing." *Id.* at 2.

Now, Ethicon seeks once again to reopen issues the parties have fully briefed and this Court has thoroughly addressed in both Waves 1 and 3 or which it failed to raise in its Wave 1-4 briefing. In essence, Ethicon seeks a third bite at the apple. Ethicon even admits that its Wave 5 Motion largely mirrors their earlier motions. *Memorandum in Support of Defendants' Motion to Exclude Certain General Opinions of Daniel Elliott, M.D.* at 1 (Doc. No. 4367) ("Ethicon's brief in this wave of cases is very similar to its brief submitted for the Wave 3 cases….") (hereinafter, "Motion"). Ethicon concedes that Dr. Elliott has not issued a materially new report or that he has any new opinions. Instead, Ethicon admits it wants the Court to revisit earlier rulings or consider Ethicon's new arguments that Ethicon failed to raise in the past. *Motion* at 1 ("Ethicon presents the following arguments that have not previously been argued and/or that have been supplemented with additional authorities…."). Ethicon's attempt to relitigate Dr. Elliott's opinions is wholly improper and an inefficient use of judicial resources. Accordingly, the Court should summarily deny Ethicon's Motion and adopt its earlier rulings.[1] Out of an abundance of caution, Plaintiffs address Ethicon's individual claims.

II. Dr. Elliott is Qualified to Testify Regarding Product Warnings.

In every one of his experts reports from Wave 1 through *Mullins* and this Wave 5 report, Dr. Elliott has consistently opined about the risks of implanting mesh, whether or not those risks

[1] Ethicon's Motion is effectively an improper motion to reconsider this Court's earlier rulings. As this Court noted in *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 649 (S.D.W. Va. 2013), "it is improper to file a motion for reconsideration simply to ask the Court to rethink what the Court had already thought through—rightly or wrongly." *Id.* (quoting *Mt. Hawley Ins. Co. v. Felman Production, Inc.*, No. 3:09–cv–00481, 2010 WL 1404107, at *2 (S.D.W.Va. Mar. 30, 2010)).

appeared in the various instructions for use ("IFUs"), and whether the undisclosed risks should have appeared in the IFUs. In fact, the language he used in all of those reports is essentially identical and Ethicon does not identify any new opinions. Now, for the first time, Ethicon insists that Dr. Elliott's testimony should be "confined" to exclude testimony about "what information should or should not be included in an IFU." *Motion* at 3.

To be clear, Ethicon had the opportunity to raise this issue in earlier briefing – yet, it has never done so. In fact, the terms "IFU", "instructions for use" or "warning" do not appear anywhere in Ethicon's Wave 1 or Wave 3 *Daubert* motions against Dr. Elliott. Especially considering the magnitude and complexity of this MDL, the Court should not permit Ethicon to serially relitigate Dr. Elliot's opinions after multiple briefs have been completed and the Court has issued multiple opinions. Ethicon waived its right to challenge Dr. Elliott's IFU/Warnings opinions. On this basis alone, the Motion should be denied.

Assuming the Court wishes to assess the substance of Ethicon's reconsideration Motion and new arguments, it is evident that Dr. Elliott is qualified to testify regarding warnings and the IFU. In fact, Defendants admit that Dr. Elliott is qualified to testify regarding the risks of implanting mesh and "whether specific risks appeared in the IFUs." *See Motion* at 3 (quoting this Court: "[A]n expert who is an obstetrician and gynecologist may testify about the specific risk of implanting mesh and whether those risks appeared in the relevant IFU…."). This is also consistent with this Court's ruling concerning Dr. Elliott in the *Cook MDL* where this Court held that Dr. Elliott was indeed qualified to identify the risks associated with the use of a mesh product and "explain[] that the IFU and defendant's product literature fails to disclose these risks." This Court held as follows:

> Cook contends Dr. Elliott is not qualified to opine on product warnings or labels….
> "Dr. Elliott's report identifies particular risks with SIS biomaterials and explains

> that the IFU and defendant's product literature fails to disclose these risks." (Id.). I agree with the plaintiff that a urologist like Dr. Elliott is qualified to make this comparison. *See Wise v. C.R. Bard, Inc.*, No. 2:12–cv–01378, 2015 WL 521202, at *9–10 (S.D.W.Va. Feb.7, 2015) (finding a urogynecologist qualified to opine on product labeling based on his knowledge and clinical experience); *see also Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 719 (S.D.W.Va.2014) (finding a urologist qualified to opine on the risks of implanting a product and whether those risks were adequately expressed on the product's IFU).

Watkins v. Cook Inc., No. 2:13-CV-20370, 2015 WL 1395773, at *10 (S.D.W. Va. Mar. 25, 2015).

Hence, the only relief Ethicon seeks is to prevent Dr. Elliott from opining on "whether other risks should or should not be included in an IFU." *Motion* at 3 & 17 (internal quotations omitted). As noted above, Dr. Elliott's reports have consistently contained opinions on these very issues and have never been challenged before. For example, in his TVT report, Dr. Elliott opines as follows:

> The IFU's Adverse Reactions section says that over correcting, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction, yet the surgeon has been previously provided with five conflicting and confusing instructions to place the tape with (1) minimal tension, (2) tension free, (3) loosely, (4) without tension, and (5) to adjust the tail of the TVT mesh until leakage is limited. This leaves the physician with no clear, articulable standard on how to avoid the serious adverse reaction of urinary retention or urinary obstruction.

(attached as Ex. C to Ethicon's Motion (Doc. No. 4364-3) at 31-32). Similarly, in his Prolift report, Dr. Elliott discusses the adequacy of the IFU as it relates to the surgical perspective and the practical impact it has on the implanting surgeon. He opines as follows:

> Hydrodissection is a surgical step used to create a space between the vagina and the rectum and/or bladder. The purpose of this step is to identify and surgically enter the rectovaginal/vesicovaginal space more easily and to reduce the risk of injury to the adjacent rectum and/or bladder. This step would seem even more important given the differences between vaginal dissections in Prolift procedures versus traditional procedures. However, the Prolift IFU makes no mention of vaginal wall hydrodissection.

(attached as Ex. F to Ethicon's Motion (Doc. No. 4364-6) at 43). Ethicon has never challenged these opinions as beyond Dr. Elliott's qualifications. There is a reason for that – he is qualified to give them.

Ethicon argues that Dr. Elliott's "curriculum vitae does not identify any additional expertise to render an opinion about the adequacy of Ethicon's IFU…." However, as reflected in Dr. Elliott's resume, he has extensive experience in the testing and development of medical devices. Dr. Elliott work on the initial animal studies and the clinical design for a male incontinence device. He also developed a rectus fascial harvester medical device for which he owns the patent. *See Dr. Elliott's Curriculum Vitae* at 22 (attached as Ex. B to Ethicon's Motion (Doc. No. 4364-2). Dr. Elliott testified concerning his experience in the development of these devices:

> Well…if you look at my CV, I was involved in transurethral enzymatic ablation of the prostate, which I worked with a researcher and the founder of the company and working with the FDA as far as getting it approved, that's when I was a resident. I worked with the design of a new artificially designed urinary sphincter for males …, so we were working on the standards with the companies, and then my own patent.

See Ex. 1, *Hammons Depo.* at 256:14-22. Accordingly, Dr. Elliott has direct experience with product design and development and the related FDA approval processes.

Moreover, Dr. Elliott has testified that he has extensive experience teaching residents about the intricacies of an IFU. In *Hammons,* he testified as follows:

> Q. As part of your training and teaching of residents, do you have occasion to teach with regard to IFUs, the instructions for use for medical devices?
> A. It would be on a daily basis with residents, especially new residents who are coming on my service, we go over the IFUs, if we're using a medical device, and then if there's a new product that comes out, we'll review those.
> Q. When you teach residents about the IFU, what are the types of things you focus on when you're actually teaching day-to-day?
> A. Well, we go over everything. It depends upon if it's a new resident or not. Let's take a new resident, typical one, it's every six weeks I have a new

> resident on my service. We sit down, we go over the IFU, we go over the procedure, how it's described and then the various different warnings or potential complications.
>
> Q. As part of that process, have you learned what it is that you're looking for in an IFU and what needs to be taught to physicians to look for?
>
> A. Oh, absolutely…

Ex. 1, *Hammons Depo*. at 10:12-11:9. This experience clearly permits Dr. Elliott to opine about what should or should not have been in an IFU. Finally, in *Bellew v. Ethicon, Inc.,* No. 13-cv-22473, Mem. Op. & Order, Dkt. No. 265, (Nov. 20, 2014), this Court held that Dr. Elliot should be permitted to testify regarding "whether Ethicon provided **sufficient guidance** to surgeons through the Prolift [IFU], the Surgical Guide, and any training programs offered." *Id.* at 24 (emphasis added).

Accordingly, the Court should refuse to entertain Ethicon's late attack on Dr. Elliott's warning opinions. Moreover, even if the Court does entertain Ethicon's new arguments, the Motion should still be denied. In addition to his training and experience as a Urogynecologist, Dr. Elliott has unique expertise in medical device development and training other physicians regarding IFUs which permits him to testify on whether certain warnings should or should not have been included in the IFUs. Finally, in the context of the Prolift litigation, this Court has already determined that Dr. Elliot was qualified to do so. Ethicon's Motion should be denied.

III. This Court Has Already Ruled That, Whether Dr. Elliott May Testify About Non-Synthetic Mesh Procedures Should Be Determined on A Case-By-Case Basis.

Defendants seek a blanket ruling preventing Dr. Elliott from testifying about non-synthetic mesh products and procedures. Defendants argue such testimony is not relevant for purposes of a design defect claim and that, even if relevant, Dr. Elliott's opinions are unreliable. Defendants' argument concerning Dr. Elliott's testimony is yet another rehash of their Wave 1 *and* Wave 3 motions. Apparently, Ethicon is not happy with the Court's previous rulings on this issue and, as

they admit in their motion, they believe "that this should be revisited." *Motion* at 4. Absent extenuating circumstances, which do not exist here, the Court should not countenance Ethicon's attempt at a belated motion for reconsideration. The Court has previously rejected these precise arguments and should do so again by adopting its Wave 1 and Wave 3 orders on these issues.

A. The Court should not issue a categorical exclusion of testimony about non-mesh alternatives when such evidence is relevant to numerous claims, including failure to warn, negligence,, impeachment, and potentially design defect.

Ethicon argues that evidence concerning non-mesh alternative treatments is irrelevant. However, the Court previously rejected Ethicon's argument during Wave 1, and the Court should not now backtrack from its sound conclusion.

Ethicon asks that this Court hold that Dr. Elliott's opinions regarding the safety of non-mesh procedures should be universally declared as irrelevant to all trials in all cases in Wave 5—regardless of the applicable state law and regardless of the evidence, claims, and arguments in a particular case. When faced with this issue previously, the Court wrote:

> *First*, Ethicon argues that Dr. Elliott should not be permitted to testify that alternative procedures are safer than Ethicon's mesh products. Expert testimony on this subject, Ethicon claims, is not relevant. The relevance of this expert testimony is better decided on a case-by-case basis. Accordingly, I **RESERVE** ruling until trial.

Wave 1 Memorandum Opinion and Order (Doc. No. 2666) at 8. This was then, and still is, the correct conclusion to reach when assessing the relevance of evidence. Under Rule 401, the standard for relevance is not high. To be relevant, evidence must have "any tendency to make a fact more or less probable than it would be without the evidence," and the fact must be "of consequence in determining the action." Fed. R. Evid. 401(a)-(b). Relevance is more appropriately addressed through motions in limine by the trial court as an evidentiary issue depending on the facts of the specific case and the applicable law.

In *Mullins*, this Court applied West Virginia law and held that "evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT." *Mullins v. Johnson & Johnson*, No. 2:12-CV-02952, 2017 WL 711766, at *2 (S.D. W. Va. Feb. 23, 2017). However, *Mullins* should not be read so broadly as to categorically exclude this evidence from all cases. For example, not all states require evidence of a safer alternative design or that such evidence be from another similar product. Moreover, at the time of the Court's ruling, *Mullins* had been limited to solely defective design claims. Clearly, such evidence may be relevant when assessing failure to warn claims, negligence claims, warranty claims or as impeachment evidence against Ethicon's contentions that its products are the "gold standard." A recent ruling from the Northern District of Illinois provides an important example of why the Court should not issue a blanket ruling prohibiting such testimony, but should instead adopt its Wave 1 ruling that this should be decided on a case-by-case basis.

In *Herrera-Nevarez v. Ethicon, Inc.*, No. 12-C-2404, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017), Ethicon requested that the court adopt the *Mullins'* ruling to exclude Dr. Elliott's testimony regarding non-mesh alternate procedures for treatment of SUI. In analyzing Ethicon's Motion, the Court noted that, under Illinois law and the particular facts of the case, the decision in *Mullins* could not simply be applied in a blanket fashion to bar all such testimony. While the court noted that the evidence may not come in to demonstrate the availability of substitute products, the court noted that, under Illinois' risk/utility test, such testimony was clearly relevant and admissible. In addition, the court held that the testimony would also be relevant to impeach Ethicon's claims that its products were the "gold standard". The court held as follows:

> Under Illinois product liability law, a plaintiff may attempt to prove that the design of a product is unreasonably dangerous using the "risk-utility" test. Factors considered when applying this test include:

> (1) the utility of the product to the user and the public;
> …
> (3) the availability of a substitute product that would meet the same need, more safely;
>
> Defendants argue that other surgical procedures are not "substitute products" whose utility and safety is relevant under factor 3, and the Court agrees. **But the availability of other safe and effective procedures to treat the same condition is relevant and admissible, as plaintiffs contend, to show the utility of the defendants' product (factor 1)—a point not addressed in the other cases upon which defendants rely. The Court also notes that this evidence is admissible to rebut defendants' contention that the TVT-O and similar products are the "gold standard" for treating SUI**.

Id. at *7 (emphasis added).

In its *Motion*, Ethicon relies upon a different Illinois remand case addressing the opinions of Dr. Shull, not Dr. Elliott. *Motion* at 5 (citing *Walker v. Ethicon, Inc.*, No. 12-CV-1801, 2017 WL 2992301, at *3 (N.D. Ill. June 22, 2017)). In *Walker*, the court held that Dr. Shull would not be permitted to testify regarding non-synthetic mesh alternatives. The different outcomes in these two cases only further confirms this Court's original ruling -- the relevance of this evidence should be determined on a case-by-case basis by the court examining the specific facts and law to be applied in a given case. Ethicon's Motion should be denied and the Court should adopt its original ruling reserving this decision for trial.

B. Dr. Elliott's opinions regarding non-synthetic mesh alternatives are based on a detailed analysis backed by reliable evidence.

Ethicon again repeats, essentially word for word, the same arguments that it leveled against Dr. Elliott in Waves 1 and 3. Ethicon does not cite to any new opinions or testimony on the subject – instead it simply seeks reconsideration of this Court's earlier ruling without meeting the standards for reconsideration outlined above. For this reason alone, the Court should deny Ethicon's repetitive, wasteful *Motion*.

In its Wave 1 Order, the Court appropriately reserved ruling on this issue until the time of trial when Dr. Elliott's clinical experience could be appropriately tested. The Court held as follows:

> Ethicon objects to the reliability of Dr. Elliott's expert testimony about whether alternative procedures are safer than Ethicon's mesh products. In my view, the reliability of this expert testimony is heavily dependent on Dr. Elliott's clinical experiences. In the abstract, experience-on its own or accompanies by little else-is a reliable basis for expert testimony. But the reliability inquiry must probe into the relationship between the experience and the expert testimony…. Here, the court does not have enough information to judge the reliability or relevance of D.r. Elliott's particular experience.
>
> In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony based primarily on an expert's clinical experiences. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

Wave 1 Memorandum Opinion and Order (Doc. No. 2666) at 8-9. The Court then adopted this ruling in its Wave 3 Order. (Doc. No. 4152) at 1.

There has been no new evidence, no further testimony from Dr. Elliott, and no trial. Hence, Ethicon's attempted redo on this issue should be denied. The Court should, as it did in Wave 3, adopt its earlier ruling reserving this issue for trial.[2]

IV. Dr. Elliott's Testimony Properly Explains the Superiority of Other Synthetic Products, Notwithstanding His Claim That Synthetic Products Overall Are Inferior.

In its Motion, Defendants state that Dr. Elliott should not be permitted to suggest that other mesh products, such as TVT-R and TVT-O, offer a safer alternative to the TVT-S. Motion at 11. Admittedly, Dr. Elliott is not an advocate for any synthetic mesh, finding all of them to pose inherent dangers. But that general opinion does not detract from the reliability of his testimony that mesh products configured differently than the TVT-S are safer. *See Nease v. Ford Motor Co.*

[2] To the extent necessary, Plaintiffs incorporate their arguments on this issue as set forth in their Wave 3 Response brief. (Doc. No. 2952, Section II).

Civ. Act. No. 3:13-29840, 2015 WL 4508691, at *5 (S.D.W. Va. July 24, 2015) (Chambers, J.) ("If a product can be made safer and the danger may be reduced by an alternative design at no substantial increase in price, then the manufacturer has a duty to adopt such a design."). Indeed, an alternative design must only be a "safer alternative." "It need not eliminate all potential risks to be safer." *Thomas v. CMI Terex Corp.*, Civ. No. 07-3597 (JBS/KMW), 2009 WL 3068242, at *16 n. 15 (D.N.J. Sept. 21, 2009). The alternative must "not be as unsafe" as the product at issue, not "safe" in the abstract. *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 573 (E.D. Pa. 2011).

When faced with a similar argument in the Wave 1 briefing this Court specifically held that Dr. Elliot was qualified to testify regarding the comparative safety of other mesh products. The Court held as follows:

> Considering Dr. Elliott's medical education and background and his vast experience treating patients with mesh complications, he is qualified to testify about whether one mesh product is safer than another. Ethicon's Motion is **DENIED** on this point.

Wave 1 Memorandum Opinion and Order (Doc. No. 2666) at 9. This is consistent with a decision in a recently remanded case.

In *Herrera-Nevarez*, the court held that Dr. Elliott's opinions were admissible despite the fact that "he does not believe that any such devices are safe…." There, the court held as follows:

> The Court also overrules defendants' contention that Dr. Elliott should not be permitted to testify that other synthetic mesh devices are safer than the TVT-O. The fact that he evidently does not believe that any such devices are safe does not preclude him from ranking them on a comparative basis. This affects only the weight to be given to Dr. Elliott's testimony on this point, not its admissibility. Defendants are, of course, free to cross-examine Dr. Elliott regarding his views of mesh devices generally and regarding any inconsistent testimony or statements he has given.

Herrera-Nevarez v. Ethicon, Inc., No. 12 C 2404, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017). Ethicon's Motion should be denied.

V. Dr. Elliott's Opinions Concerning Lighter Weight/Larger Pore Size Mesh Are Reliable.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section III.C of Doc. No. 2952.

VI. Dr. Elliott's Opinions Concerning Mechanical Cut vs. Laser Cut Are Reliable.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section IV of Doc. No. 2952.

VII. This Court Has Already Reserved Ruling on Whether or Not Dr. Elliott May Offer Opinions Regarding Testing, Adverse Events and Training.

Defendants claim Dr. Elliott should not be permitted to testify regarding Ethicon's failure to test its devices, adverse event reporting and training. Motion at 13-17. Again, Defendants have made these precise arguments since Wave 1. Importantly, in Wave 1, this Court correctly reserved ruling on these issues "because the scope of relevant testimony may vary according to differences in state products liability law" and the facts of the particular case. This Court concluded as follows:

> I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Wave 1 Memorandum Opinion and Order (Doc. No. 2666) at 13. This Court later adopted this holding in its Wave 3 Order noting, "the Court will refrain from engaging in the extremely inefficient practice of continuously reexamining the qualifications, reliability, and relevance of dozens of experts and their numerous opinions." *Wave 3 Memorandum Opinion and Order* (Doc. No. 4152) at 2. The Court should again adopt this reasoning and deny Ethicon's *Motion*.

As noted, Ethicon's briefing on this issue is identical to its briefing in Wave 1 and Wave 3. The only change Ethicon identifies since its earlier briefing is a trial court decision in Illinois regarding an entirely different expert. *See Motion* at 15 (discussing *Walker v. Ethicon Inc.*, 2017 WL 2992301 (N.D. Ill. June 22, 2017) (addressing Dr. Shull)). However, *Walker* only adds

additional support to the Court's decision to allow the appropriate trial court to apply the laws and facts of the case before it when determining the relevance of this testimony. *Walker* demonstrates that the Court's approach to reserve ruling actually works.

As Ethicon's briefing on this, with the exception of its citation to *Walker*, mirrors its earlier briefing, Plaintiffs will not burden the Court with a re-recitation of its opposition to these points. Instead, Plaintiffs, acknowledging the Court's admonishments about inefficiencies, adopt their Response to these issues from their Wave 3 brief. *See* Section V of Doc. No. 2952.

VIII. Dr. Elliott's Testimony Regarding Problems With the TVT Mesh Are Reliable.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section VI of Doc. No. 2952.

IX. Dr. Elliott Will Not Offer Opinions Related to the TVT-Exact.

Ethicon argues that Dr. Elliott, never having issued a TVT-Exact report, should not be permitted to provide opinions regarding the TVT-Exact. Plaintiffs agree. Dr. Elliott will not offer any opinions regarding the TVT-Exact device.

X. This Court Has Already Held That Dr. Elliott's "Marketing" Opinions Are Proper.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section VII of Doc. No. 2952.

CONCLUSION

To the extent Ethicon refused to adopt its earlier arguments and chose instead to make new arguments or tweak old arguments, the Court should decline to engage in Ethicon's patent attempt at reconsideration. As noted, Dr. Elliott's reports have not materially changed and Ethicon fails to identify any new opinions or testimony. The Court should reject Ethicon's attempt at a third bite at the apple and simply adopt its earlier Wave 3 rulings.

Date: August 29, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2017 I electronically filed the foregoing **PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.** with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Jenelle Cox
Jenelle Cox

EXHIBIT 1

IN RE: PELVIC MESH/GYNECARE LITIGATION	:
PATRICIA L. HAMMONS, Plaintiff,	: COURT OF COMMON PLEAS : PHILADELPHIA COUNTY : MAY TERM, 2013
vs.	:
ETHICON, INC., et al.,	:
Defendants.	: No. 003913

November 21, 2015

Oral sworn videotaped de bene esse at deposition of DANIEL S. ELLIOTT, M.D., held MAZIE SLATER KATZ & FREEMAN, LLC, 103 Eisenhower Parkway, 2nd Floor, Roseland, New Jersey, before Margaret M. Reihl, RPR, CCR, CRR, CLR and Notary Public, on the above date, commencing at 9:20 a.m.

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INDEX

EXHIBITS

PRIOR TESTIMONY OF DR. ELLIOTT REFERENCED:

TRANSCRIPT OF BELLEW TRIAL DAY 2, March 3, 2015

TRANSCRIPT OF BELLEW TRIAL DAY 3, March 4, 2015

TRANSCRIPT OF DEPOSITION November 15, 2012

TRANSCRIPT OF DEPOSITION November 16, 2012

Page 6

THE VIDEOGRAPHER: All right. We are now on the record. My name is Thomas Keighley, and I am a videographer for Golkow Technologies. Today's date is November 21st, 2015. The time is approximately 9:20 a.m. This video deposition is being held in Roseland, New Jersey at 103 Eisenhower Parkway at the offices of Mazie Slater Katz & Freeman. We are here in the matter of Pelvic Mesh, specifically Hammons versus Ethicon, Inc., et al. This is for the Court of Common Pleas, Lehigh County. The deponent is Dr. Daniel Elliott.

Counsel, your appearances will be noted on the stenographic record, and the court reporter is Peg Reihl, if she could swear in the witness and we can proceed.

... DANIEL S. ELLIOTT, M.D., having been duly sworn as a witness, was examined and testified as follows ...

MR. ISMAIL: Just if I can note for the stenographic record, I guess now for the video as well, there was a cross-notice filed for this notice -- of this deposition in the MDL to which Ethicon filed a motion to quash. That

Page 7

motion is still pending. I just want to make sure that objection was preserved and noted on this record.

MR. SLATER: My understanding is just from seeing some correspondence that the plaintiffs maintained their cross-notice, and I guess that will be decided by the federal judges.

MR. ISMAIL: Yes, thank you.

BY MR. SLATER:

Q. You can look at me when you speak, Dr. Elliott. It's actually fine either way, okay?

A. Okay.

MR. SLATER: Are we ready to proceed? Did you swear the witness? You swore him in? Okay, great. Okay. Let's proceed.

DIRECT EXAMINATION

BY MR. SLATER:

Q. Good morning, Dr. Elliott.

A. Good morning.

Q. Dr. Elliott, we've marked for identification a document P2239. Can you tell us what that document is?

Page 8

A. This is my current Curriculum Vitae.

Q. That's a list of your background, your education, your qualifications, that type of thing?

A. That's correct.

Q. Would you tell the jury what your profession is, please.

A. I am a urologic reconstructive surgeon at the Mayo Clinic.

Q. And tell the jury where you're a licensed physician.

A. In the state of Minnesota.

Q. What is the Mayo Clinic where you work?

A. It's a large tertiary care medical center, meaning -- tertiary care just means the end of the line type thing, you don't get referred on from there, which is a multi-specialty practice.

Q. And where is that located?

A. In Rochester, Minnesota.

Q. Tell the jury a little bit about your educational background, where you went to medical school, your residency, the training you did from that point forward briefly.

A. Medical school was in southern California at Loma Linda University School of Medicine. Then I

Page 9

did a one-year general surgery at the Mayo Clinic in Rochester, Minnesota, followed by five years of urologic surgery training at Mayo Clinic. I was asked to come on staff and then did a one-year advanced surgical fellowship at the Baylor College of Medicine in Houston.

Q. Would you tell the jury about your medical practice, what you do day to day?

A. It's the reconstructive urology means we're taking care of problems that are occurring in the pelvis, complications dealing with males and females. Majority of my practice, probably roughly two-thirds is female, one-third is male.

Q. What are the types of conditions you treat?

A. Breaking down into stress incontinence, both male and female, pelvic organ prolapse for females and then the complications arising from those treatments.

Q. Do you teach, do you have any teaching appointments?

A. Yes. I'm a teacher at Mayo as far as teaching residents, rotations on my service, lectures for medical students. Also, I guess you could call it

Page 10

an educator with the SUFU, which is Society of Urodynamics & Female Urology, I'm on the education --
Q. Say that a little slower. What is SUFU?
A. Society of Urodynamics & Female Urology, that's the large, arguably the most elite in the United States society dealing with female urology and pelvic floor function, and so I'm on the education committee for that. So that there's education as far as future education for both residents, though, mainly for individuals who have already graduated and are in practice.
Q. As part of your training and teaching of residents, do you have occasion to teach with regard to IFUs, the instructions for use for medical devices?
A. It would be on a daily basis with residents, especially new residents who are coming on my service, we go over the IFUs, if we're using a medical device, and then if there's a new product that comes out, we'll review those.
Q. When you teach residents about the IFU, what are the types of things you focus on when you're actually teaching day-to-day?
A. Well, we go over everything. It depends upon if it's a new resident or not. Let's take a new

Page 11

resident, typical one, it's every six weeks I have a new resident on my service. We sit down, we go over the IFU, we go over the procedure, how it's described and then the various different warnings or potential complications.
Q. As part of that process, have you learned what it is that you're looking for in an IFU and what needs to be taught to physicians to look for?
A. Oh, absolutely, but that's not just with IFUs. That's also as far as paper writing and reviewing of manuscripts.
Q. Do you have involvement with the peer-reviewed literature?
A. Yes.
Q. Tell the jury your involvement -- first of all, what is the peer-reviewed medical literature?
A. Peer reviewed for any article coming out in a reputable journal, it will be reviewed by multiple individuals within your peer group, so that's why it's peer reviewed. So I'm a reviewer for some 16 different journals, more or less, and so your responsibility is to obtain a manuscript, look at it critically. The goal is to find weaknesses in the paper, strengths in the paper, what is lacking, where it can be improved.

Page 12

Q. Do you act as a peer reviewer?
A. Yes, for I say roughly 16 journals.
Q. Have you published articles in the peer-reviewed medical literature yourself?
A. Yes, I have.
Q. Do you have experience treating prolapse with mesh?
A. Yes.
Q. Tell the jury that experience.
A. Surgically treating prolapse is dealing with only transabdominal or robotic. I have never placed transvaginal mesh for prolapse.
Q. Do you perform procedures to treat prolapse that do not involve mesh?
A. Yes.
Q. Tell the jury about that.
A. Well, there's going to be a spectrum of different conditions, bladder, rectum or enterocele where the intestines fall down, and I have been trained and daily or every other day perform transvaginal prolapse repairs, but not with mesh.
Q. What do you use to do those procedures?
A. It's the traditional colporrhaphy is the name of it using sutures, absorbable sutures.

Page 13

Q. Have you attended at any point training with regard to mesh kits like the Prolift®?
A. Yes.
Q. Tell us about that.
A. It was with AMS, I was an instructor, they had combined incontinence and prolapse. I taught the incontinence part, but also the cadavers right next to me were where the instructors were teaching the transvaginal prolapse repair, so I went over and then did that with those instructors.
Q. And that was for the AMS Apogee and Perigee?
A. Correct.
Q. Is that a similar product to the Prolift®?
A. Very similar, yes.
Q. Over the years have you become involved in treating patients who had Prolifts® placed by other doctors at other locations where they've had complications?
A. Correct, yes, I have.
Q. Tell us about your treatment of women with Prolift® complications or other mesh complications as well.
A. That began roughly 2006, 2007, in that

time frame, I don't remember the exact time, but that was the ballpark that we started seeing various different complications like vaginal extrusion, organ erosion and more commonly pelvic pain.

Q. In your practice, have you treated patients who have had complications from the Prolift®?

A. Yes.

Q. And is that what you were just describing? Is that among the patients that you've treated with those conditions?

A. Correct.

Q. As part of your treatment of patients with Prolift® complications, did you become familiar with the Prolift® system?

A. Yes.

Q. What did you do?

A. Well, initially, besides just when these complications would come in, you know, I'm attending meetings, national, international meetings, we would be discussing it with colleagues in the field, urogynecology colleagues, my institution. We would go back online and look at the product, because, remember, I chose not to place the product, so we had to learn about how is this put in, reviewing of manuscripts. We

always do that, a PubMed search, which is the largest search engine looking for articles about this and management of complications.

Q. Did you have the opportunity to see the IFU at some point as part of your practice as well?

A. Yes, with the Prolift®, yes.

Q. Was it helpful to you in treating the complications to learn about the Prolift® system?

A. From the IFU?

Q. The IFU and the other material and conversations you had, did you find that was helpful to you in treating the complications?

A. Discussing with colleagues and review of manuscripts was. I'd have to say that the IFU for the procedure was helpful, how it was going, the management of the complications, no.

Q. How prevalent has been your treatment of mesh complications, including Prolift® complications, in your practice?

A. Well, it depends what time frame you're talking about. 2005, uncommon; as the time goes on, more and more common, such that in any given week I'm seeing three to five or maybe more patients with various different mesh complications, including the

Prolift®.

Q. Have you actually spoken at any national meetings to other physicians about the treatment of mesh complications?

A. Well, numerous times, most -- numerous times and most recently in February, again, at that SUFU meeting, Society of Urodynamics & Female Urology, where I was the invited lecturer on management of complications of the mesh.

Q. Have you previously been qualified as an expert in a Federal Court case with regard to the Prolift®?

A. Yes.

MR. ISMAIL: Objection, 403.

MR. SLATER: We offer Dr. Elliott as an expert in the fields of urology and female pelvic medicine and reconstructive surgery.

MR. ISMAIL: We'll reserve for our qualifications for cross.

BY MR. SLATER:

Q. Doctor, in the course of your testimony, I'll be asking you to -- if you have opinions on certain issues.

You realize that, right?

A. Yes.

Q. In the course of your testimony, do you understand that if you offer an opinion, whether I ask you for an opinion or if you offer it in the course of your testimony, that it must be to a reasonable degree of medical certainty?

A. Correct.

Q. So that I don't have to keep repeating that phrase over and over, can we have an understanding that if you offer an opinion, it will be to a reasonable degree of medical certainty, or you will tell us otherwise?

A. Yes.

Q. Okay. What I'd like to do now is you have a list of materials reviewed, correct?

A. Yes, I do.

Q. And just tell us what that list is.

A. It's a fairly brief summary of all the materials that I've reviewed pertaining to the mesh and specifically Prolift®. Number one was the medical literature that I reviewed, that would have been mainly through PubMed, which is the largest search engine for medical literature, clinical and preclinical studies. Ethicon and J&J internal documents and videos, surgical

videos usually. Ethicon and J&J current and former employees' depositions, which there's a large number of those, which we did not glean out each one, but there's a large number. Depositions of the Ethicon consultants and the New England Journal of Medicine editors and, lastly, Ethicon and J&J product labeling and marketing documents, like the IFU and patient brochures.

Q. Those categories of information, you've set forth a reliance list of what you've relied on in this case?

A. Yes.

Q. Okay. With regard to the Johnson & Johnson and Ethicon internal documents that were not publicly available, was that significant information to you in forming your opinions in this case?

A. Very much so, yes.

Q. Why is that?

A. Because as a surgeon active in practice, attending meetings, reviewing of the medical literature, that gives me one side of complications or what is known. What I was unaware of prior to this litigation is what was the degree, severity of the complications that were known prior to that and was not available to the -- say, the average doctor on the

street.

Q. Let's go to an exhibit that's on the top of your pile there P1306, which is Prolift® patient brochure.

Is this a document you're familiar with?

A. Yes, it is.

Q. Is this a document you've relied on in part in forming your opinions in this matter?

A. That is correct.

Q. What I'd like to do is just for illustrative purposes turn to Page 5, please, and there is a diagram of normal pelvic anatomy.

And the jury will have this up on their screen to see. Can you just tell the jury very simply what of significance is shown in this simple illustration?

A. Well, it's a cartoon or a schematic of the female pelvis in a coronal or going down the middle, and it's just showing the anatomy with the bladder, urethra, vagina and uterus. It's a quite simplified anatomy view for a patient.

Q. Now, let's turn to the next page, Page 6, and there's an illustration of a cystocele, and can you tell the jury what they're seeing there?

A. Yes, this in comparison to the first

picture, which was normal anatomy, the second one now has a schematic -- again, understand it's in a very simplified form, which there's nothing wrong with that, but it's just showing the anterior bladder wall falling down, which is called a cystocele.

Q. Why does that happen? What is it physiologically that happens that allows the bladder to bulge down into the vagina?

A. Be multiple different factors, increasing age, childbirth, possibly hysterectomy, obesity, chronic cough, factors like that that increase the strain on the pelvis that would have the tissue weaken over time and then fall down.

Q. When you refer to the tissue, you're talking about the tissue of the pelvic floor?

A. That's correct, the vaginal tissue, though, technically, it's the tissue underneath the vagina that's holding things up and it's weakened because of those aforementioned factors.

Q. Let's turn to the next page. Let's turn to Page 7 of the patient brochure. There's an illustration of a rectocele. Can you just tell us simply what that is showing.

A. Yeah, a rectocele, think of it as just the

opposite of what I described of where the bladder is falling down, as we say, into the vagina, this is where the rectum is ballooning up into the vagina, again, because of those other issues of pregnancy, childbirth and weakening of the tissues.

Q. There's a diagram on Page 7 of uterine prolapse. Very simply, what is that?

A. Again, similar to the other issues, this is where the uterus is falling down, again, due to lack of support or weakened support.

Q. Is surgery required for all pelvic organ prolapse?

A. No.

Q. Is it an elective surgery or a surgery that must be done in the vast majority of cases?

A. It is a quality -- it's very important to emphasize this, it's a quality of life problem, meaning the patient is really in charge as far as the decision-making. So for the majority of individuals in my practice, observation or conservative therapies are done. It is very rarely in the United States a necessity that surgery has to be done.

Q. Let's turn to the list of treatment options. It would be the second PowerPoint slide,

Page 22

treatment options for pelvic organ prolapse, and I'll ask you to briefly go through the list and tell us what each of them -- what each of these options are?

A. It's a summary that made up of options or historical options for treatment of pelvic organ prolapse in women. As I mentioned, it's a quality of life problem. So the first option is observation and being conservative, just reassuring the patient that if it's not bothering them, don't do anything. If it's minimally bothersome, you know, you may or may not choose to do something.

Next option is a pessary, which is a -- kind of think of it like a plug, a silicone or a plastic plug being placed in the vagina to help hold things up. Historically, that was done a lot, now a little bit less so, but still it's a conservative, nonsurgical option.

Q. Basically, it would be placed under the bladder to hold the bladder up?

A. It's placed in the vagina underneath the bladder to either hold up the bladder, hold up the uterus or hold up the rectum, dependent upon what problem they're trying to fix.

The next one is the traditional sutured

Page 23

repairs, like the colporrhaphy. Colporrhaphy just means repair of the vagina, so you can have an anterior colporrhaphy of the bladder, posterior colporrhaphy for rectum, and that's using sutures, the traditional type of repair, which I do very commonly.

We also mentioned briefly here the sacrospinous ligament fixation and uterosacral ligament fixation. Those are for what's called vault prolapses, where the whole vagina is falling out, so through the vagina, you can suture it to various different structures to provide support.

And then you have the transabdominal sacrocolpopexy. This is a procedure that can be done either with an incision or done laparoscopically or done with a robot, which is my preferred route.

Q. What does that mean laparoscopically or with a robot?

A. The procedure is fixing the vagina up to the sacrum. It can be done with an incision, where it's opened up, or using a laparoscope, which is cameras through little ports, four or five ports or using a robot, which is basically a robot attached to the cameras looking in. It's a different way of doing it.

Page 24

The next is biologic grafts. This is where you can use either tissue from a tissue bank, like cadaveric tissue, which is not the patient's, but it's human, or you can use xenografts, which is coming from a different source, like pig or cow. And then you also have synthetic grafts, which is a mesh that's placed in the vagina.

Last on the list is the mesh kit, in this particular case the Prolift®, but it can be multiple other mesh kits out there.

Q. What are the most prevalent surgical procedures for the treatment of prolapse?

A. Currently as far -- well, again, it depends upon what type of prolapse you're talking about, because there's going to be a lot of different ones.

Q. Let's talk about, for example, a cystocele.

A. Cystocele would be an anterior colporrhaphy. The traditional nonsutured repair would be most common.

Q. Are the various abdominal sacrocolpopexies that you described both open and laparoscopic or robotic prevalent as well?

Page 25

A. They're very common, but, again, that's for total vaginal vault prolapse, yes, and depending on the various different regions, like in the south, it is the most common procedure performed for that common problem.

Q. Doctor, I'm going to now hand across the table to you what we are marking as P2810, and this would be the actual Prolift® anterior repair kit, and what I'll ask you to do first is just to show the jury what the Prolift® kit is. We've obviously started to open it to save time, and the camera will show the instruments and tell the jury what we're seeing there.

A. Well, important probably, let's go back to the basics. It comes as a kit. So what the surgeon gets is a kit in a box.

Q. And I'll hand you the box, which also has the booklet in it as well.

A. Which the nurse brings this to you, takes it out of the box. The surgeon opens it up, and so it's a contained kit, as opposed to multiple different pieces. It's a self-contained operation, a kit.

So then you're going to have the various different components of the kit, which you will have the trocar, however long that is, 15 inches or so

curved. It's curved for gaining access, we can go into it later, as far as through the obturator foramen or how this goes in, so it goes in through it and --

Q. What does that mean? If you're going to say something technical, you might as well tell the jury, obturator foramen.

A. You have the pelvis, male or female, doesn't matter, you have the obturator foramen, which are the holes off to the side, kind of look like this. As I explain it to residents, I go like this is how it is. So you have the vagina here and then these obturator foramen which are the big bones attached to it with overlying muscles, gracilis, abductor longus, a bunch of -- four or five different muscles overlying this.

So when you're gaining access to the vagina, you will go through the obturator foramen from the outside in and go down to the vagina. So there will be a surgeon's hand in the vagina to grab this. Again, this is the trocar gaining access going through those muscles, through the obturator foramen into the vagina. You should have this loaded up here, then there's the cannula that actually goes over this.

So when the surgeon goes in, then he pulls it

on out, so we don't have to go into detail now, but a cannula is another part of it. And then the -- you'll have a retrieval system here, and then, lastly, you'll also have the mesh. Now, again this is an anterior mesh.

Q. What is that used to treat?

A. This is to treat anterior prolapse, okay, the bladder, a cystocele, okay.

Q. So if the bladder is dropping down on to the vagina or into the vagina, this is for the treatment of that condition?

A. Correct. There will be three different types of meshes predesigned, precut meshes, one for anterior like this one here. This will show up very well, may show up a little better like this that can be seen with arms on it, four arms going out those obturator foramen, which I had mentioned. The posterior will have a different configuration, and then the total will be a combination of the anterior and posterior.

Q. When you showed the guide and the cannula, is that ultimately to set the tunnels to pull the arms back out of the body?

A. Correct, correct, yeah.

So this will go from the outside through the obturator foramen into the vagina. This is pulled out. The retrieval device is placed through it and then the mesh is pulled through it. So at the at the end of the procedure, this is very important, all of these, the trocar, the retrieval device and the cannula are no longer with the patient. The only thing that's remaining is the mesh.

Q. Now, we have here -- we've marked this as Exhibit 2292, a total repair kit, and what I'll ask you to do, keep it separate, I really just want you to be able to -- to pull out the mesh part.

MR. ISMAIL: Objection to the relevance.

BY MR. SLATER:

Q. If you could, please show the jury the total Prolift® implant.

A. I'll just keep it in the plastic here, actually show it a little better here.

So you have the total Prolift®, where you have the anterior component of it or part right here, that's what I showed just a second ago (indicating).

Q. That's for treatment of a bladder prolapse?

A. Bladder or anterior prolapse, a cystocele.

Then you have the posterior aspect up here with the various different arms, again, the arms are configured differently because they're exiting out the -- they're not going through the obturator foramen, they're actually going through the buttocks. So you can get an idea of the volume of the meshes and the arms and the shape. This is treating a total vaginal vault prolapse.

Q. And the posterior part of the Prolift®, that's to treat a rectocele or rectal prolapse?

A. The posterior is for rectocele, that is correct, yes. The total would be for anterior cystocele, enterocele like the intestines are pushing down and rectocele, so it's treating the whole vault.

Q. I'll take that.

Doctor, in your career have you ever used the Prolift®?

A. No, I have not, by choice.

Q. Do the other doctors at the Mayo Clinic use the Prolift®?

MR. ISMAIL: Objection, lack of foundation.

MR. SLATER: Rephrase.

BY MR. SLATER:

Page 30

Q. Did the other doctors at the Mayo Clinic use the Prolift®?
MR. ISMAIL: Objection, lack of foundation, hearsay, 403.
THE WITNESS: No, all by choice separately, just chose back in 2005 in that time frame not to use it.
BY MR. SLATER:
Q. Why did you chose not to use the Prolift®?
A. I didn't see a need for it.
Q. What do you mean by that?
A. In my practice we had good success, good quality of life, low recurrence rate, and I didn't see a purpose for it.
Q. When the Prolift® first came out, did you look to see if there was data to support the use of the Prolift®?
A. Right when it first came out, no. We're going back a lot of years now. I remember looking and reviewing it because there was a lot of interest in female urology. This is my first year -- five years in practice, and it was new, it was different, and so I looked into it. I don't recall the literature I reviewed at that point in time, but, again, I just

Page 31

decided I didn't see a need.
Q. Okay. I'd like you to look now at Exhibit 1593 and this is a Prolift® professional education PowerPoint slide deck.
Are you familiar with this document?
A. Yes, I am.
Q. Is this something you've relied on in forming your opinions?
A. Yes, it is.
Q. What I'd like to do is turn you towards the back, actually, about seven or eight pages from the back, there's an illustration of the anterior implant position.
Do you have that?
A. This one?
Q. Yes. Great.
A. Doesn't look like we have a page number on it.
Q. There's no page numbers on it but --
A. That one.
Q. Great. It will certainly be up on the screen for the jury.
Can you tell the jury what this is showing, this simple schematic?

Page 32

A. This is, assuming we're on the same page -- we are on the same page, correct?
Q. Yes.
A. Okay. This is a schematic, again, a cartoon or a simplified version of the actual anterior mesh in-situ, meaning in the patient and where it goes, where the arms go and things.
Q. What are the structures that we see, just to orient us?
A. Well, it's quite simplified because a lot of the important things are not there. But you can see the bladder, you can see underneath it the mesh and then under that you can see the vagina. And then you see the rectum and you see the obturator foramen and various different ligaments around the pelvis, but, again, it's quite simplified.
Q. The bladder would be to the front, the rectum would be to the back as the jury sees this?
A. As you go down you have bladder, mesh, vagina, rectum from top to bottom.
Q. If you turn -- this is actually the 55th page of the slide deck, just for the record. If you turn back one page to the -- actually turn forward one page, okay, on the 54th page of the slide deck, I

Page 33

believe it is -- it says Gynecare Prolift® Total Implant Position.
What is that showing us?
MR. ISMAIL: Objection, relevance, 403.
THE WITNESS: Okay. That's showing -- it's a continuation of the volume of mesh that's put in. It shows the anterior and posterior mesh in place as it would theoretically be supporting the bladder, the apex of the vagina and then the posterior aspect which is where the rectum would be.
BY MR. SLATER:
Q. Okay. Now, what I'd like to do, if we could, is go through some animation video clips. Are these video clips that you have selected and that you have reviewed as part of your review of this case?
A. That is correct, yes.
Q. Are these animation videos something you've relied on in forming your opinions?
A. Yes.
Q. Do you, in your opinion, feel they would be useful to you in demonstrating aspects of the procedure and illustrating your opinions in this case?
A. Very much so, yes.

Page 34

Q. Okay. We are going to play the video clips with no sound, and they are short video clips, and the first one is a short one. It's 501 for the record.

MR. ISMAIL: Just we object under 403 to the playing or showing to the jury of any of the video of the actual surgery itself.

MR. SLATER: Okay. We're starting with the animation clips.

MR. ISMAIL: Fair enough.

MR. SLATER: Is there an objection to the animations?

MR. ISMAIL: Depends what you show.

MR. SLATER: There's not a blanket objection, initially?

MR. ISMAIL: Not a blanket objection.

BY MR. SLATER:

Q. Okay. Doctor, what we're going to do, before we show this, clip 501 we're going to put it up on the screen, and then you'll just tell the jury, we'll pause it about halfway through when it gets set up, and then you can tell the jury what they see, okay.

(Video played.)

BY MR. SLATER:

Page 35

Q. What is that showing us?

A. Okay. Again, it's just showing the anterior Prolift® mesh, as it would be placed in the patient as far as somewhat of its orientation, and then the female pelvis in what's called the dorsal lithotomy position, just the way you operate, a woman on her back, legs up in stirrup and then access to the vagina. And then you can see underneath it is the pelvic bones, how they would be in the woman when she's on her back.

Q. Just for the record, you're turned a little to the side because you're looking at a screen on the wall?

A. Yes, I am. There's a screen over here.

Q. Okay. We're going to now go to clip 502. What are we going to see here?

A. On 502?

Q. Yeah, let's play -- actually, let's play it and then if you want to have him pause it or you certainly can tell him to pause it at a certain time and explain what we're seeing.

A. Yeah, it's just describing -- you can pause it a second there very quickly. It initially highlighted the arms, which is a very key component to the Prolift® mesh, which makes it unique compared to

Page 36

the other operations I discussed, where the arms would be going through the obturator foramen. That's why it highlighted the more out -- proximal vagina and then deep vagina. So those arms go in different locations.

Q. What I actually want to do now is I want to go back to the start on this clip.

A. Okay.

Q. Let's go back. We're not going to be able to pause it because it's going to be played in other courts potentially, and they're not going to be able to know when you paused it. So what I'm going to do is I'm just going to have the clip played.

A. Okay.

Q. And this is -- I'm just saying this for everyone in the room, probably realize that was kind of silly what I just did, hope everybody had a good giggle out of it. We're just going to show it from the beginning when I'm ready to start, and then you'll just narrate as it goes, and then when it's done, you can explain if there's anything else you have to explain.

So let me start over. That was just for everyone in the room to know -- get their jollies here.

Doctor, we're now going to show animation clip 502. As it plays, would you please explain to the jury

Page 37

what they're seeing.

A. Sure. It's a schematic again showing the mesh with highlighting the various different arms that go through the obturator foramen, which I've discussed just a little earlier and then place it in the vagina how it will be done, with an incision. They described there a fairly small incision. Now you've turned sideways, and then they'll place the mesh through that.

Q. And the mesh is placed through the vagina through a vaginal incision?

A. Correct.

Q. Next we're going to go to clip 504A, and what we'll do is, again, we'll show it and please tell the jury what of significance they're seeing, please.

A. Okay. Now, this is a surgeon with a finger placed through the vagina through the vagina incision, now, those trocars, which I showed just a little while ago, going through the obturator foramen through multiple different muscles, there they show one of the muscles. There's other ones. Again, there's four or five different large muscle groups that it goes through, through the vagina, on to the surgeon's index finger, and then they will first place the distal most, see there, toward the opening of the vagina. There's

Page 38

where the first one goes through, ideally through the arcus tendineus, which is an anatomical strong structure.

Q. Okay. Now, let's go to animation clip 505, please, and just again narrate through for the jury what is significant to you.

A. Again, we have the schematic and now the arms are already placed through. We've actually missed a step. There's another video in there describing how they placed the other ones, but this is how the mesh wraps through the retrieval device and then will be pulled out through the skin, through the vagina, through the skin and out.

Q. And I think -- well, rephrase.

Let's go to clip 506 now, and can you tell the jury what they're seeing there.

A. Okay. Again, this is the placement through the retrieval devices of all the four arms that will go through the vagina and out the obturator foramen through those cannula that I described earlier, and now the cannulas are being removed and the mesh is then being slid into place. The cannulas then are removed. Here's where it shows the mesh lying flat in there, again, in the cartoon fashion.

Page 39

Q. Doctor, we're not going to go through the total or posterior Prolift® procedures in the interest of time.

The video animation clips that we just showed for the anterior procedure, are they a fair demonstration of those steps of the procedure in a general sense of what is done to get the mesh into the body and the arms out?

A. Well, it's very -- it's a schematic. I don't know -- I would argue on the word fair, but it's showing how it goes through because it's very simplified form of it, yes, let's put it that way.

Q. What I meant is does it, in a general sense, demonstrate what would happen in the posterior or total procedures as well?

A. Yes, in a very general sense, but I'd say it would be misleading, though.

MR. ISMAIL: Objection, move to strike, nonresponsive.

BY MR. SLATER:

Q. Doctor, the clip that we just -- the clips that we just saw of the anterior procedure, do they generally show how the mesh in an animated, simple form is placed into the body and the arms are pulled out?

Page 40

A. Yes.

Q. Doctor, what is the mesh material in the Prolift®, what is it called?

A. It's -- well, the basic is polypropylene mesh.

Q. And what is it called, what's the name of the mesh?

A. Gynemesh®.

Q. And was that originally developed to be used in the pelvis or for another use?

A. Another use.

Q. What's that?

A. For hernia repair, abdominal hernia repair.

Q. And that was called Prolene Soft when it was developed for hernia?

A. That is correct.

Q. When Gynemesh® mesh started -- Prolene Soft mesh started to be marketed for use in the pelvis, it was first marketed in about 2003; is that correct?

A. Roughly in that time frame, yes.

Q. And when it was first sold as Gynemesh® PS, was it sold in a kit like this or was it sold differently?

Page 41

A. No, it was not in a kit, it was just a sheet of polypropylene.

Q. And what did doctors do with that mesh when it was first sold as Gynemesh® PS?

A. The surgeon would trim it, tailor it to the given patient and place it through the vagina.

Q. And just would use a portion of the mesh to help support a suture repair as-needed?

A. That is correct. It would be to tailor, to repair whatever they're repairing.

Q. We're going to talk more about this a little later, but do you have an opinion as to whether the use of Gynemesh®, just cutting a portion of it and placing it in the vagina for a particular patient's needs, whether or not that is a safer alternative than the Prolift® with the larger amount of mesh and the arms that we've seen?

MR. ISMAIL: Objection, lack of foundation. I don't believe this is a disclosed opinion.

BY MR. SLATER:

Q. You can answer.

A. I would be very careful what I say -- I would say it would be a safer procedure. I do not

Page 42

agree with it being safe, but it is safer than the kit with arms, et cetera.
Q. And we'll talk more about it later, but very succinctly, what's the reason why?
MR. ISMAIL: Objection, lack of foundation, undisclosed opinion.
THE WITNESS: There would be multiple factors. The largest one would be the sheer volume of mesh, but then also the trocars with the arms going through the various different muscle groups, because that is going to fix this mesh in a completely different way.
BY MR. SLATER:
Q. Doctor, next exhibit is PLT0062, not a PowerPoint, but it's an actual document.
MR. ISMAIL: Copy. While you're at it, can I have the other one. I didn't want to interrupt while you did the video. Thank you. These are the 504s and the 506s?
MR. SLATER: They are, and we can -- we'll get you the actual clips if you don't have them. They're exactly the same as what was utilized in Bellew, so you guys should have them, but we can have them Dropboxed or sent

Page 43

over to you.
MR. ISMAIL: Thank you.
BY MR. SLATER:
Q. Okay. Doctor, I've handed you PLT0062. Is this a medical journal article you are familiar with?
A. Yes, it is.
Q. Is this an article that you feel and believe to be medically reliable in the field?
A. Yes, it is, yes.
Q. Is this something you've relied on in forming your opinions?
A. Yes.
Q. First of all, who wrote this article?
A. Well, it's a TVM group, as they call them. There's multiple different authors involved, six, I believe.
Q. What was the role of the TVM group, this group of doctors from France, what was their -- very simply their role with the Prolift®?
A. Well, a group of physicians got together, these surgeons that are mentioned here, in France, as you stated, to devise this new technique for prolapse repair using the polypropylene mesh.

Page 44

Q. If you could, turn to the fourth page is Page 579, and what I want to focus on in the bottom right corner, there's a -- I guess a blowup of a microscopic picture of the -- or a close-up picture of the soft Prolene mesh. That's the mesh in the Prolift®?
A. That is correct.
MR. ISMAIL: Objection, hearsay.
THE WITNESS: Yes, that's correct.
BY MR. SLATER:
Q. And just focusing on that one box that says soft Prolene on it, what are we seeing there? What's of significance?
MR. ISMAIL: Objection, hearsay. I don't want to keep interrupting. I have a standing objection to hearsay to the use of this article. Okay. I'll keep objecting. Objection, hearsay. Sorry, I didn't mean to interrupt.
MR. SLATER: Let me just ask, I don't understand your hearsay objection. It's a medical literature.
MR. ISMAIL: Objection, hearsay.
MR. SLATER: You think they're not useful,

Page 45

you can't use medical literature in a trial?
MR. ISMAIL: This article is hearsay.
MR. SLATER: You don't have to object to the use of my articles on the hearsay basis anymore during this deposition. That's preserved.
MR. ISMAIL: I'm probably going to, given that I think we have a disagreement as to whether learned treatises are hearsay or not.
MR. SLATER: All right. But I'm saying I'm granting you a standing objection to my use of learned treatises as hearsay that is inadmissible, so you don't have to object it because you can -- every time I use medical literature, you can object to it and say it was hearsay and shouldn't be allowed to be used, so that way we can move through, is that okay? It will help me to not have you objecting when I'm already agreeing you have a preserved objection.
MR. ISMAIL: I appreciate that. What I'll do is every time you introduce a new article, I'll object to that one as being hearsay, and if I have a standing objection to the use of

Page 46

that particular article, I won't keep interrupting.
MR. SLATER: You have a standing objection to my use of medical journal articles.
MR. ISMAIL: I have an objection to this article, Exhibit 62, Plaintiffs' Exhibit 62, as hearsay, and I appreciate the standing objection to the use of this article.
MR. SLATER: Sure, and it's for the record PLT0062.
MR. ISMAIL: Yes. Thank you.
BY MR. SLATER:
Q. Okay. Doctor, I'm going to start over.
On Page 579 of this article, there is an illustration and a close-up picture of soft Prolene mesh.
Do you see that?
A. That is correct, yes.
Q. Is that the mesh material in the Prolift®?
A. Yes, it is.
Q. What is of significance that we're seeing here?
A. Well, they're just showing -- you have to take it in all -- there's four different photographs.

Page 47

Q. We're only looking at the soft Prolene picture.
A. They're just showing the mesh, the weave of the mesh, the space of the meshes.
Q. What do they call -- what are those spaces referred to as?
A. The pore size would be the easiest one, the gate in between them, the space in between the various meshes.
Q. We have -- you see there's some larger spaces and they have a thread right through the middle.
Do you see those?
A. Yes, I do.
Q. There's also knots and spaces there. What are those referred to as?
A. Well, again, there's a -- all the meshes have a different weave to them. So this is the weave of the mesh and the areas where it's all knotted, as you mentioned.
Q. So it's showing the actual appearance of the pores and the interstices between the mesh?
A. Correct, on a relatively microscopic or magnified view.
Q. When the mesh is in the body after the

Page 48

surgery, and now that this incision is closed, what is supposed to happen? What was intended to happen with the healing process and with the mesh in the body?
A. Well, theoretically, as you see here, the picture has large pores, now, again, this is magnified, so we have to take that, but, theoretically, you are going to have the tissues grow through those to get nice healthy tissue in between those pores, that's in theory. It would be like a scar net is the kind of phrase that was used. But, again, that's in theory what would happen.
Q. What actually occurs in practice based on your review of the materials, the medical literature, your medical experience, all the materials you reviewed, what is it that actually occurs?
MR. ISMAIL: Objection, lack of foundation, 705.
THE WITNESS: Okay. In my daily practice on physical exams in people with Prolift®, what actually happens when that Prolift® gets in there, or any mesh, for that matter, not just Prolift®, but let's just talk specific to Prolift®, the mesh is going to be pulled, the pore size is going to decrease, and then

Page 49

instead of getting this intergrowth through the holes of the mesh and have nice healthy tissue, you then get a scar plate. So the scar forms around this.
So where it's important for me is then on physical exam, when you do a pelvic exam, you feel this fibrotic or wooden, what you kind of describe it as, again, this firmness within the vagina.
BY MR. SLATER:
Q. What is it that leads to the development of scar tissue, what is it about the interaction of the mesh in the body that leads to that?
A. Well, that's a long, drawn out conversation because what you've got, you've got a foreign body --
Q. Let's do it not the long, drawn out conversation version.
A. All right, we'll be specific. Mesh is not human, it's foreign. You put it in the body, the body perceives it as foreign. The body's natural response is to try to get rid of it, and the process starts to create this foreign body reaction, which increases the scar tissue, that causes the mesh to contract or the

Page 50

tissue to contract around it, which then perpetuates the problem. That's why it's a progressive problem. So it's a long, drawn out conversation. That's a very succinct answer.

Q. As part of the foreign body reaction, is there any inflammatory response as well?

A. Well, that is part of it, okay. The body perceives the mesh as foreign, which it is. The response of the body is to create inflammatory response. So as long as that foreign body is in there, you're going to have an inflammatory process.

Q. With regard to the size of the pores in the Prolift® mesh or any mesh, is there an understanding as to whether or not larger spaces or smaller spaces are better in terms of the healing process?

A. The larger the space, the space in between the mesh, the reduced inflammatory and foreign body reaction you're going to have.

Q. There's been reference, and tell me if you're familiar with it, to a 1 millimeter pore size in all directions under strain.

Is that a concept that's of any significance to you?

Page 51

A. Yeah, it's a very important concept.

Q. Why is that?

A. Saying that -- again, you made a very good point there as far as when it's in the body, under strain. It doesn't matter what it's doing on the table. As I hold up this mesh, that doesn't matter. What matters is is when it's in the body and when it's being pulled on when the woman is walking, coughing, doing activities, what those pores do. Those pores contract down, then you're going to start this whole cascade, the scar plate, the inflammatory response, foreign body reaction.

Q. What happens to the pores when the Prolift®, as we've seen in those schematics, gets put into the body, what happens to the pores?

A. Collapses.

Q. What do you mean by that?

A. Means, again, we have this picture of these large pores, okay, when you start to pull on it, when you place it, just the arms, you're going to have to pull on those arms, you're going to have to tension this, and then those pores go from this to collapsed down like this (indicating). When that happens, now the body can't grow through it, like that scar net I

Page 52

described. Now you get that caking, and we can feel it when we do physical exams on Prolift®, the banding we call it, feel out lateral in the vagina, and you feel this rod, for lack of a better phrase, you touch it, it hurts. It's a whole cascade of everything I've mentioned several times now.

Q. What is contraction or shrinkage, what does that mean?

A. That's when, again, we go back to this foreign body reaction, inflammatory response, the body is trying to healing itself. The only way it can is by creating scar. When that happens, the scar contracts down, pulling the mesh. The mesh is the ultimate responsibility, but it pulls on it, okay, and the significance of mesh contraction is pain, because, like I mentioned in that video, where these trocars are going through all those muscles and mesh is going through those muscles, muscles hurt when you start to pull on them. So as the mesh contracts, pulls together, pulls on those muscles of the pelvis and it causes the pain.

Q. Doctor, if you could go back to the professional education PowerPoint, 1593, it's the larger one right there, top left, and it's about the

Page 53

tenth page in, and actually I counted them, I think it's the tenth page, and there is a slide that says "Mesh Use in Hernia Surgery" and has a picture of rebar.

A. Yes.

Q. Is this of significance to you, this illustration and the language next to it?

A. Yes.

Q. Tell the jury, first of all, it says, "Much like rebar in concrete, the stress at any one point is distributed over the entire area of the graft."

Do you see that?

A. Yes, I do.

Q. Now, have you seen anything in any medical literature or any material you've ever seen that shows that when the Prolift® is placed, it actually has this distribution of stress across the entire mesh, like they say in the engineering rebar?

A. Well, no, it's the exact opposite, actually.

Q. And so using this diagram, what's the significance of this picture of rebar?

MR. ISMAIL: Objection, lack of

foundation, 705.
THE WITNESS: Well, the rebar analogy is accurate and completely inaccurate at the same time. Yes, I agree, it's a very strong substance, unbending, but when it's placed in the human body, that's not what you want. You need to have something dynamic that can move, and so that's why I say it's correct and it's incorrect. It's very, very strong, but that's not what you want having placed in the vagina.
BY MR. SLATER:
Q. If rebar has to be removed from the sidewalk, you take the jackhammers and chop down into the concrete and get it out?
MR. ISMAIL: Objection, 403.
THE WITNESS: Which I have done in between high school and college, and it is a bear. That's why I never do it anymore. Did it once and that's it.
BY MR. SLATER:
Q. When mesh has to be removed, how does that analogy apply to the human body?
A. Well, I don't have the luxury of not being able to do that, like I can do with rebar concrete. It

is very similar. You have to cut, you have to use big scissors. We just did one two or three days ago, large scissors to cut through this. It's very stuck, and it's very tedious surgery because it can be fixed to the bladder, very difficult -- the bladder is thin, get into it, you got a mess. Posteriorly on the rectum or up top on the intestines, and you can't get it all out. It's a very tedious -- we call it a train wreck because it's very difficult to get out.
MR. ISMAIL: Objection, move to strike, nonresponsive, 403.
BY MR. SLATER:
Q. Doctor, with regard to the difficulty in removing the mesh, do you have an opinion as to whether or not that is medically safe or unsafe aspect of the Prolift® system?
A. It's quite unsafe.
Q. Doctor, with regard to the reaction of this large mesh implant that you've shown us with the human tissue, the foreign body reaction, the inflammatory response, do you have an opinion as to whether that is medically safe or unsafe?
A. It's unsafe.
Q. We're now, Doctor, going to go to some two

clips of video from actual surgical videos from Ethicon from their professional education department, correct?
A. That is correct.
Q. Now, have you reviewed and selected these short clips to help illustrate your opinions?
A. Yes, I have.
Q. Would they be helpful to you in demonstrating relative aspects of the Prolift® procedure?
A. Definitely.
Q. The first one that we're going to use is 5701, and what we'll do is we'll show the video and while it's playing, please, just as you did before with the animations, narrate and tell us what is of significance to you in explaining your opinions on the Prolift®.
MR. ISMAIL: Objection, 403, to showing the video.
THE WITNESS: It's going to be a surgical video. It's going to be sort of graphic for people not used to this, but it's showing the mesh trying to be put through the vagina. They're doing actually a stay stitch there first. And now they've got the retrieval

devices already in there, and there they're actually stuffing the mesh in there, because, remember, I showed you the mesh, it's a large volume of mesh, the vagina is small. You have to stuff it in there. So that was actually a very good description or visual image for everybody to just kind of see how you have to push it through there.
BY MR. SLATER:
Q. When the mesh gets pushed in that way, what impact does that have on the mesh itself?
A. Well, there can be multiple different factors. You're pushing it through vagina, which can cause infection of it, contamination of it. You can distort the meshes if you're pulling on it, and it's not going to lay flat.
Q. Let's go to clip -- and one other thing, in that image, in that video there were -- did we see the cannulas actually coming out that were placed for an anterior procedure?
A. Yeah, we saw on that one the retrieval devices were already in. The cannulas had already been removed. The retrieval devices were there on the mesh arms, they hadn't been pulled through yet.

Page 58

Q. Let me ask you this: In the image we could actually see the white cannulas. Were they still in the body, not the next clip, but the clip we just saw?
A. I thought the cannulas had been removed already. I'd have to look at it then. If the cannulas were removed, then just the -- yeah, the cannulas are still there, yes.
Q. Let's go to clip 5702, the next clip, and tell us as it plays what we're seeing and what's significant, please.
MR. ISMAIL: Objection, 403.
THE WITNESS: Okay. So now we see he's pulling out the cannula and then the mesh arms extending out through the obturator foramen, and, again, what's important to note about that as we saw earlier the size of the mesh arms, which are about one centimeter, a little larger going through those cannulas, which are just a couple millimeters and they're rolled, so it will cause the mesh to roll, the arm meshes to roll.
BY MR. SLATER:
Q. And what we'll do now is go to the next

Page 59

PowerPoint slide, which is a side by side comparison of a still shot from the animation and from the video we just saw, and can you tell the jury what of significance this shows?
MR. ISMAIL: Objection, 403.
THE WITNESS: Okay. The biggest thing to me is if you look at the cartoon first, for me it's on the left, that the mesh arms are laying flat, but then, in reality, when it goes into the human, you can't have a 1 to 1.5 centimeter mesh arm go through a cannula that's a couple millimeters and not get it to roll. So if you were able to zoom in there where it comes out of the skin, it's going to be rolled. That's going to also collapse those pores and start that whole cascade of inflammation, foreign body reaction, scarring.
BY MR. SLATER:
Q. When the mesh is pulled through the cannulas, as we see illustrated on these still shots, what happens to the mesh when it's being pulled through the cannulas, what happens to the pores and the mesh itself?
A. It can collapse, it will collapse. If

Page 60

you're pulling on it with more than, what, 2.3-kilos, which is roughly 12 pounds of force, which is not much, and you'll pull on it, those pores -- remember, they start like this, you pull on them and they'll collapse on you. Again, that increases the foreign body, prevents that growth through the interspaces and starts that whole foreign body cascade I talked about.
Q. With regard to the amount of force you just stated, was that confirmed to be the amount of force used during the procedure by Scott Ciarracca?
A. Correct.
MR. ISMAIL: Objection, lack of foundation.
BY MR. SLATER:
Q. Do you have an opinion -- and we can take that down now.
Do you have an opinion, Doctor, as to whether or not the arms and the cannulas are necessary to treat pelvic organ prolapse?
A. I have an opinion, yes.
Q. What's your opinion?
A. They're absolutely not essential. They're counterproductive.
Q. And do you have an opinion as to whether

Page 61

or not the use of the arms and the cannulas, as we've seen, is medically safe or unsafe?
A. It's unsafe.
Q. Why is that?
A. Again, like I've mentioned, as far as just multiple different issues. Number one, the rolling going through the muscles, which will cause contraction and pain. Then also it fixes the vagina. The vagina is a dynamic organ. As a woman stands, lays down, coughs, it's going to move. Those arms are going to cause it to be fixed, and then so when she does activity, that's what causes the pain, so pull on the muscles and other structures.
Q. Let's go to the next PowerPoint slide. We have in front of you a slide we've titled tension free and, first of all, we have little footnotes there with respect to the deposition testimony where these pieces of information came from.
Have you read those depositions?
A. Yes, I have.
Q. And have you relied on those depositions in part in forming your opinions?
A. Yes.
Q. What is tension free? In the context of

Page 62

Prolift® and the concept of the Prolift®, what was the concept of tension free?

A. Well, tension free, if we're talking about the mesh just sitting on the table versus the mesh in real life, okay, I deal with real life. I don't care what it's like on the table. I care what's in the patient.

So as it sits on the table, it's going to be tension free, there's no pulling on it. But in order for you to put it in the woman, it's impossible to have something be tension free. If there's no tension, the prolapse still exists, so it's -- you can't have it in real life in the patient.

Q. Now, the first thing we have on this, on documents, I'm just going to ask you about a phrase tension free, meaning the mesh is in unstretched condition as if laying on a table, okay.

Do you have an opinion as to whether or not in actual use in the body, the mesh can be placed tension free, as described there?

A. It cannot be.

Q. And just very simply why? I think you might have talked about this already, but just very simply.

Page 63

A. Again, like we've talked about that the human vagina is not a table, okay. It's going to be moving, lifting, walking, and it's going to -- in order to hold a prolapse, which is everything is falling down, you've got to hold it up; therefore, there's going to be tension on that device. Placing it through the body is going to require tension. You've got to pull it through and adjust it.

Q. And we saw the video of how it was pushed through the vagina and then how the arms were used. Does that impact on that opinion as well?

A. Again, that's consistent with my opinion.

Q. Tension on the mesh plus contraction equals pain. What is the significance of that?

A. That's what I referred to earlier, that if mesh is pulled with a minimal amount of force, 12 pounds of pressure, those pores will collapse. That will cause this foreign body reaction, inflammation and scarring, that causes the mesh to contract, article like by Tunn, et al., 65, 80% mesh contraction. When that happens, structures are pulled on, specifically muscles or nerve intergrowth, and that causes pain.

MR. ISMAIL: Objection, move to strike, hearsay.

Page 64

BY MR. SLATER:

Q. Doctor, look at the next exhibit on the pile. Take that slide down.

It's Exhibit P2227, and it's an e-mail written by Piet Hinoul, medical affairs director, September 3, 2009.

Is this an e-mail you're familiar with?

A. Yes, it is.

Q. What I'd like to do is turn to the second page. There are a series of asterisked bullet points. We're going to go to the last one on the page, which starts there is an issue.

Do you see where I'm reading? It's the last asterisk.

A. I'm there, yes.

Q. I'm going to just read it for the record, and then I want to ask you about this, okay?

A. All right.

Q. "There is the issue of being able to adjust, fine tune the position of a Prolift® mesh. This must also be addressed up front; the mesh and Prolift® can indeed be adjusted, but that is because one overcorrects (surgeons not adjusting by loosening after having pulled it too tight have all the problems

Page 65

with pain, incontinence, obstructed defecation), again we adjust to make it tension free not the other way around."

And then reading a little further, this tension free concept is something we own, we must also use it here. Doctors like the sound of it (despite the fact that most do not understand it).

Now, is that language I just read written by a medical affairs director, Piet Hinoul, of significance to you?

A. Yes.

Q. Why?

A. Well, they acknowledge multiple different things in here. Number one that surgeons don't know how to tension this, and, number two, the tension free concept is something that sounds very good. The company wants to protect that marketing aspect. That's a different story here, but the biggest one is that the surgeons don't know how to tension this.

MR. ISMAIL: Objection, move to strike, nonresponsive.

BY MR. SLATER:

Q. Let me ask you this question: I just want to clean something up in case -- that was a great

Page 66

objection, just got to always hedge against that.
Doctor, this language that I just read, why is -- well, let me just say something right now. When you answer this question, don't talk about marketing at all, okay. So I'm going to ask the question again.
Doctor, I just read language written by Piet Hinoul, medical affairs director. Why is that language significant to you with regard to the tension free concept?
MR. ISMAIL: Objection, lack of foundation.
BY MR. SLATER:
Q. From a medical standpoint, why is that important?
A. From a medical standpoint, you know, again, multiple different aspects of the tendency of surgeons to tighten this up too much. They don't understand how to tighten this. It hasn't been explained to them well enough. And so -- and that tensioning problem is one of the root sources for all the various different complications, pain, obstruction, incontinence, et cetera.
Q. When the mesh is placed under tension, in your opinion, does that lead to any negative side

Page 67

effects?
A. Yes.
Q. What is that?
A. Again, that's going back to this issue, it's the root source of the problem that tensioning causes the pores to collapse, can cause the tissue integration, which then leads to scarring, inflammatory response and subsequently pain.
Q. Doctor, we'll take that document down.
Doctor, there was a theory that this large mesh implant would result in a more durable, longer lasting anatomic repair than with a suture repair.
Was that part of the concept?
A. Correct.
Q. When we say the focus was on an anatomic -- correction, the anatomic positioning, what does that mean?
A. It means we have to kind of go back almost a certain step. When you have a woman with prolapse, it means the bladder or structure has fallen down to the wrong spot. So you have anatomy is can you restore it to a normal position, okay. So that's where we talk about anatomical repair, putting it back up to where it should be.

Page 68

Q. Now, over time I've seen reference to functional outcomes, quality of life outcomes.
What does that mean?
A. That's the other aspect of prolapse, just -- and it's a quality of life problem. Just because you have an organ that's fallen down, say the bladder, articles like Whiteside, et al. 2004 talk about what we're really after here is this woman's quality of life, is she happy, is the support, the surgery provided an improvement of quality of life.
MR. ISMAIL: Objection, move to strike, hearsay.
BY MR. SLATER:
Q. Doctor, I'm going to ask you the question again. Don't refer to, in case the objection was well done, the Whiteside article in answering the question.
MR. SLATER: I assume that's your objection, right?
MR. ISMAIL: Yes.
MR. SLATER: Okay. Trying to move this along.
BY MR. SLATER:
Q. Doctor, when we talk about functional outcomes, quality of life outcomes as opposed to

Page 69

anatomic, what's the distinction?
A. Anatomy is just looking at has that prolapse been repaired or not. It's not taking into account a patient's quality of life, sexual function or just symptoms of prolapse, fullness, pressure.
Functional outcomes are looking at if you do this surgery is the woman pleased with the outcome as far as the improvement of the prolapse symptoms.
Q. Doctor, please look at the next exhibit, which is PLT1093. This is an article titled "Incidence and risk factors for reoperation of surgically treated pelvic organ prolapse" authored by Dällenbach and some other authors in 2011.
Are you familiar with this article?
A. Yes, I am.
Q. Is this article, in your opinion, medically reliable and authoritative in the field?
A. Yes, it is.
Q. Is this an article you've relied on in forming your opinions?
A. Yes.
Q. Why is this article important, in general terms?
MR. ISMAIL: Objection, hearsay.

Page 70

BY MR. SLATER:
Q. Rephrase. Why is this article of significance to you?
MR. ISMAIL: Objection, hearsay.
THE WITNESS: Because what it's doing is looking at and trying to correct somewhat of the incorrect thinking we have as far as the true recurrence rate and reoperation rate following prolapse repairs. So what this is doing is breaking it down and looking at the true incidence, which records it at roughly -- I think their conclusion is like 6 to 12% reoperation for prolapse.
BY MR. SLATER:
Q. Doctor, if you turn to the page that has the discussion on it, I'm not seeing the page numbers. It's the third page from the end.
A. Okay, I'm there.
Q. And it says -- you see discussion?
A. Yes, I do.
Q. Okay. It says in the first sentence, our study suggests that the risk of reoperation after prolapse surgery is relatively low and associated with variables indicating pre-existing weakness of pelvic

Page 71

floor tissues.
What is that -- is that of significance to you?
MR. ISMAIL: Objection, hearsay. Do I have a standing objection to Exhibit 1093?
MR. SLATER: You have a standing objection to every one of my articles as hearsay and any questions on them.
MR. ISMAIL: I understand, but I'm going to identify each one to which I have the hearsay objection, and then I won't interrupt your exam on this article.
MR. SLATER: Yeah, please don't.
MR. ISMAIL: Standing objection to 1093 on hearsay.
MR. SLATER: I'll start again.
THE WITNESS: And can you -- I'm trying to track exactly where you are.
BY MR. SLATER:
Q. You see Discussion?
A. Yes, I am under Discussion.
Q. Okay. I'm going to actually go now to the second paragraph. You see it says, "we systematically"?
A. Yes, I'm there.

Page 72

Q. I want to read this and ask you what, if any, significance this has to you.
We systematically searched Medline, (search terms: "reoperation for surgically treated/managed pelvic organ prolapse, recurrent pelvic organ prolapse, follow-up studies," all languages, from 1966 to 2010) and found few studies reporting the incidence of reoperation for recurrent prolapse. Most authors measured the combined risk of reoperation for surgically treated prolapse and urinary incontinence, thus overestimating the rate for pelvic organ prolapse reoperation alone. The risk of reoperation for prolapse or urinary incontinence of 29.2% frequently quoted as a reference in further studies results in a retrospective cohort study of 384 women. It goes on to talk about following them prospectively, and at five to ten years their reoperation rate was 13% and 17%. And then says the risk of re-operation for prolapse alone during a five-year follow-up was much lower (1.5%) in another study.
Do you see that?
A. Yes, I do.
Q. Is that of significance to you?
A. Yes.

Page 73

Q. Why is that significant to you in forming your opinions?
A. Number one, you cannot describe the reoperation of prolapse if you're also combining it with stress incontinence, they're two separate problems, okay. So it's going to falsely elevate both of them in reality, and so that's why they're talking about the common report of 29.2%, which I've actually rooted my studies, so it's not accurate. So what they did then is look at the true reoperation rate, and so for this one, you know, they are down to 1.5% at five-year follow-up, which is obviously a very small number.
Q. Now, they're talking about treating patients with suture repairs, correct; that's what they did?
A. That's correct.
Q. Okay. Turn to the next page, please. And it's actually the second to last page of the article, there is a Table 6 at the top left corner, and if you come down that left column, about two-thirds of the way down the page, there's a sentence that says, "The anatomical recurrence rate in our cohort is probably higher; but, in most cases, women are asymptomatic and

Page 74

do not require surgery."
Is that significant to you?
A. That is correct.
Q. Why?
A. Because, again, when you have -- this is a prolapse is a quality of life problem, okay. So what you want to do and what success is is the woman asymptomatic and her symptoms of prolapse cured. So they're saying as the anatomy may have come down, but the women are fine.
Q. On the right-hand column almost directly across the page, it says based on previous reports, we would expect a high right of reoperation, which is not the case. Our study supports the idea that conventional vaginal surgery is effective to treat pelvic organ prolapse.
Is that of significance to you?
A. Yes.
Q. Why?
A. Because it's showing that the traditional types of repairs actually work to relieve the patient's symptoms.
Q. And, finally, on the last page in the last paragraph, based on our data and recent studies, we

Page 75

believe the risk of reoperation for recurrence after pelvic organ prolapse reconstructive surgery to be between 6% and 12% rather than 30% as previously described.
Is that significant?
A. Yes.
Q. Why?
A. Again, it's stating that the 29.2 or 30%, as they state here, reoperation rate is much higher than in reality, it's down to around 6 to 12%.
Q. Based on the Dällenbach article, your understanding of the overall medical literature, your experience and your knowledge in the field, do you have an opinion as to whether or not the Prolift® was necessary in order to treat pelvic organ prolapse as compared to the existing traditional alternatives?
MR. ISMAIL: Objection, hearsay, cumulative.
THE WITNESS: Based upon this study and others and my own personal experience, it was not needed.
BY MR. SLATER:
Q. Meaning that the alternatives were adequate?

Page 76

A. Correct.
MR. ISMAIL: Objection, same, cumulative, sorry.
MR. SLATER: Go off for a second.
THE VIDEOGRAPHER: Off the record. The time is 10:32, we are off the record.
(Brief recess.)
THE VIDEOGRAPHER: The time is 10:41, and we are back on the record.
BY MR. SLATER:
Q. Doctor, in the course of asking you about your background, I neglected to ask you one question.
Are you a board certified physician?
A. Yes, I am.
Q. Who are you board certified by?
A. By urology, American Urologic Association and then also by combined boards of urology and GYN for female pelvic medicine and reconstructive surgery.
Q. And what is the significance of those board certifications?
A. The first one is stating that you have gone through -- for me it was six years of urologic training, including general surgery, and that the board recognizes you having taken three different exams that

Page 77

you are a qualified urologist.
The second one is subspecializing in female urology and pelvic floor reconstruction, so the boards of GYN, urology came together because we have a lot of overlap, and I've had this certificate available since 2013.
Q. Okay. Doctor, we're now going to go to the next exhibit, which we've marked P0049, and if you could, first looking at the front page, what is this document?
A. This is just the -- as it states at the top, the Evaluation of the TVM technique for Ethicon.
Q. It says clinical study report dated June 27, 2006, and it says the principal investigator was Michel Cosson, Dr. Cosson. Is that what this technically is, is this clinical study report for the French TVM study?
A. That is correct and their 12-month data.
Q. And let's now turn to Page 4. There's a section that says -- and just very, very briefly and simply, what was the French TVM study; what were they doing?
A. They were looking at the feasibility and the results and the complications, efficacy of the TVM

Page 78

technique.
Q. And when you say the TVM technique, that's what ultimately became the Prolift® procedure?
A. That is correct, yes.
Q. And we look at the statistical methods section, and I'm going to try to avoid much of the statistical jargon and let you explain it simply, but about six or eight lines down, there's a sentence that says, the criterion for success was that the upper 90% two-tailed confidence interval (same as the tail on a one tail 95% confidence interval) did not exceed 20%. Otherwise, the study would be deemed a failure, as it would not show that the prolapse rate was less than 20%.
In layman's terms, what is that telling us?
A. Any time you set up a study you establish criteria beforehand of what you expect is defining as success, so they're doing a very good job of that.
Then they get into a bunch of statistical stuff, the two-tailed confidence interval, et cetera. It's detailed statistics of how they prove something is a success or not, and then their bottom line saying that if they have a prolapse recurrence greater than 20%, that they deemed the procedure as a failure.

Page 79

Q. And when they see -- well, I'll withdraw it. Let me move forward. Let's go down to the results and conclusions section, the actual results now. It says, the primary effectiveness variable was recurrence of prolapse at 12 months post-procedure (failure of procedure), with failure being defined as a prolapse of International Continence Society Stage II or more or a surgical re-intervention.
So that's telling us the criteria for success or failure?
A. Again, they're going on -- they're defining what we define, the studiers, the researchers as a success or failure. So they're saying the International -- ICS, International Continence Society Stage II or more or surgical re-intervention is failure.
Q. When they say recurrence of prolapse, does that just mean after you've treated it does it come back at some level?
A. Correct, that's anatomic recurrence, yes.
Q. And they call Stage II being a recurrence. What does that mean?
A. That just means that you grade prolapses. There's multiple different grading systems, but you

Page 80

grade them. Easiest way is grade 1 is essentially completely normal. Grade 2 is little bit of prolapse, grade 3 is more, grade 4 is coming all the way out. That's just a brief way of describing it. So they're saying Stage II where it's dropped down a fair bit is a failure.
Q. I'm reading now further in the results and conclusions section. The results show a failure rate at 12 months of 18.4% with a 90% confidence interval of -- I'm going to start over.
I'm going to read now within the results and conclusions section. The results show a failure rate at 12 months of 18.4% with a 90% confidence interval of 11.9 to 26.6. Thus the study did not meet the predefined criteria of a failure rate of less than 20%.
What does that mean?
A. It means that at 12 months, which is the absolute minimum you would want to do a study for prolapse, 12 months would be very, very minimum, that based upon the statistical analysis they were above the 20% predefined failure rate. So, subsequently, based upon this data, the TVM system, which became Prolift® did not make anatomical success, did not reach their criteria.

Page 81

Q. And just to be clear, they gave a range of 11.9 to 26.6, that's the confidence interval where they're saying we can take these results and apply them more broadly, and that's the statistical range?
A. Correct. That's when statistics -- advanced people with biostatistics come in and do their math, and so I have to trust their math on that one. So they're telling me it did not meet the success of the procedure.
Q. The second paragraph of the results and conclusions says the secondary effectiveness parameters show a failure rate at six months of 12.6%, 90% confidence interval, 7.3 to 20.1%.
What is that telling us?
A. Again, they're just saying at the short term at six months, the raw number of 12.6 had already recurred, so it was a fast recurrence.
Q. And the 20.1% with the confidence interval, it was already over 20%?
A. Yes, I'm sorry. Yes, at six months already they had exceeded their predefined success or failure number.
Q. Turn to Page 5, please, the very top of, again, the results and conclusions section, moderate or

Page 82

severe vaginal retraction was reported in 11 (12.6%) patients.
What is that telling us?
A. Vaginal retraction is what we've already mentioned earlier on scarring of the mesh. They happen to use the word retraction. It's the same thing, but in these surgeon's hands, high volume surgeons, they had 12.6 of moderate or severe contraction, mesh contraction.
Q. Based on the results of the TVM study, do you have an opinion as to whether or not the Prolift® was a safe and effective procedure to be marketed on the widespread basis it was?
A. Let's break it down in two. You said safe and effective. So, number one, effective, no. These researchers, it failed. It did not meet the effectiveness, which is purely anatomic.
Safety-wise, that was addressed in the second one, that 12.6, so not a small number, had vaginal retraction that was visible or palpable.
So on both those aspects, no.
Q. Did you see Axel Arnaud's deposition testimony where he testified that the French TVM study showed a 20.7% exposure rate at one year?

Page 83

MR. ISMAIL: Objection, leading, lack of foundation.
THE WITNESS: Yes, I read that.
BY MR. SLATER:
Q. Is that of significance to you?
A. Very much so, yes.
Q. Why?
A. Because he stated what the true incidence of the vaginal mesh exposure was in the study at 20.7, which the study itself quotes a lower number.
MR. ISMAIL: Objection, lack of foundation.
BY MR. SLATER:
Q. Is a 20.7% exposure rate, in your opinion, a safe rate for that complication?
A. No.
Q. Why not?
A. Well, not just my opinion, my colleagues, internal documentation say, you know, that is a very common number. It is a very high number, and that ultimately leads to reoperation, which is increased risks there, so, no, it's not a safe number.
Q. Okay. Let's go to the next PowerPoint slide. I want to ask you about design challenge is a

Page 84

controlled foreign body reaction, and we cite to Piet Hinoul.
Do you have an opinion as to whether or not the Prolift® achieved the design challenge of a controlled foreign body reaction in women?
MR. ISMAIL: Objection to the use of the slide.
THE WITNESS: It did not.
BY MR. SLATER:
Q. And what's your basis for that?
A. The basis is going to be multifactorial. My personal experience day-to-day examining patients, operating on patients, review of the medical literature, a review of internal documentation, attendance at national, international meetings, discussion with colleagues, that the mesh did not have a controlled foreign body reaction and had complications associated with it.
BY MR. SLATER:
Q. The concept of a fine balance, if there's too much fibrosis, it would be unsafe, as testified to by Piet Hinoul.
Do you have an opinion as to whether or not the Prolift® achieved that fine balance?

Page 85

MR. ISMAIL: Objection, argumentative, 705.
THE WITNESS: It did not meet that fine balance.
BY MR. SLATER:
Q. And what's your basis for that opinion?
A. Again, just like I just mentioned, all those aforementioned criteria. No small issue is my daily or weekly examination of patients with Prolift®, medical literature, review or our attendance at meetings, international, national colleagues, discussing those issues.
Q. And with regard to the concept of too much fibrosis would be unsafe, why is that? I think you've talked about it, but let's just make it clear for the record right now.
A. Again, fibrosis is a response to the mesh and the decrease in pore size, the small pore size, which causes foreign body reaction, chronic inflammation, which the body responds naturally, just causing scarring.
So too much fibrosis is a result of all those other issues, okay, come together, and that's what causes the pain, the vaginal extrusion, et cetera.

Page 86

Q. There's a concept of scar plating or bridging fibrosis. You may have -- I think you talked about it earlier, but is that relevant in this context?

A. Yes, that's what I'm referring to, the scar plating is the result of the implantation of the device, the decreased pore size, inflammation, foreign body reaction, more scarring, and then you get that plate. Remember, I keep going like this. This is where it goes -- theoretically goes through the tissues versus plating and scarring.

Q. Let's go to the next PowerPoint slide.

With regard to the concept of design requirements, are you familiar with testimony from Ethicon witnesses about their design requirements?

MR. ISMAIL: Objection as argumentative, use of the slide, leading, lack of foundation.

THE WITNESS: Yes, I've read all those depositions.

BY MR. SLATER:

Q. I want to ask you about a specific design requirement. The mesh lays flat. Assuming that the mesh laying flat is a design requirement for the Prolift®, do you have an opinion as to whether or not the Prolift® met that design requirement?

Page 87

A. It did not meet that requirement.

Q. And what's your basis for that?

A. Okay. Basis, again, goes down the line of my physical exam of these patients on a weekly basis, including those with Prolift®, the medical literature, internal documentation, national/international meetings, discussion with colleagues.

Q. With regard to whether the mesh lays flat, we've seen some materials and some videos here today, does that enter into your opinion on that?

A. Yes.

Q. Why is that?

A. The mesh, the Prolift® kit, when the mesh comes it's a one size fits all, okay. It's analogous to saying everybody should fit in the same size of shoe, doesn't happen. So if that mesh is, let's say, this long and you have a woman who is shorter or the surgeon does not place it in the correct location or the sufficient location, that mesh is going to bunch up, it's not going to lay flat. It can't.

Q. With regard to the arms and the use of the cannulas, does that impact on your opinion?

A. Yes, see, the arms, see, that's also another aspect, the arms are going to be pulling on

Page 88

this. The pelvis is a dynamic structure, okay. It's not just like always laying down at the time of surgery. A woman is going to be getting up, she's going to be moving, she's going to go right, she's to go left, she's going to lean over, and that's going to make the vagina have to move.

The pelvis is an incredibly complicated structure, and so these internal organs have to move. Now if they're anchored in and have these arms going out, going through muscles and that's anchored in because of the scarring, foreign body reaction, et cetera, it can't do that. So when those mesh arms pull, it's going to be causing the pain and also the vaginal extrusion and other factors -- other issues, excuse me.

Q. When the mesh arms came through the cannulas and they come through the cannulas in the body, are they flat or has the shape been changed?

A. No, just like I pointed out, that's why the video was so important, that's why I said the original cartoon is not fair because it shows them laying flat. You cannot have a flat piece of mesh this wide go through a cannula -- a cannula this big, you can't have a one centimeter thing come out flat, it

Page 89

won't be, can't do it, physically impossible.

Q. Okay. A design requirement of the mesh incorporated safely into the woman's pelvis.

Assuming that to be one of the design requirements, do you have an opinion as to whether that design requirement was met with the Prolift®?

A. It was not met.

Q. Why is that?

A. Again, that goes back to everything we've said over and over. The mesh has to be safely incorporated in the pelvis, so no scarring, no extrusion, no fibrosis, no pain, and that was not achieved.

Q. Doctor, we're going to take that slide down. We're going to go to the next exhibit. Please look at Exhibit PLT0067 titled "Complications from vaginally placed mesh in pelvic reconstructive surgery."

Are you familiar with this article?

A. Very much so, yes.

Q. Is this article, in your opinion, medically reliable and authoritative in the field?

A. Yes, it is.

Q. Is this an article that you've relied on

in forming your opinions?
A. Yes.
Q. Okay. What is this article?
MR. ISMAIL: Objection, hearsay.
THE WITNESS: This is written with my colleagues in the urogynecology department at Mayo. Roberta Blandon, she was a resident. I didn't know her, but I know Gebhart, Trabuco and Klingele well. I operate every other week with three of -- two of those.
And so this is summarizing -- this is in the very early days, it was published in 2009, submitted I think probably prior to that in the early days of the mesh complications. It's one of the first papers out there talking about those complications.
BY MR. SLATER:
Q. And I just want to ask you a question because we're going to talk a little bit more about the complications described in this paper. Rephrase.
I want to ask you something baseline before we talk about -- rephrase.
I want to ask you a baseline question.
When contracted Prolift® mesh is explanted,

when that's being done and when it's taken out, what is -- we've seen what it looks like out of the box and how it feels. How is it -- is it any different when you're actually removing it from the body?
A. It's a mess.
Q. What do you mean by that?
A. It's a very difficult surgery. The mesh -- there is actually a picture of explanted mesh here. Here we go.
The picture that they show on Page 529 is explanted mesh, okay. I, as a surgeon, look at this and that is a human's body attached to that mesh. They had to use big scissors to cut through this, and you look at the burned edges, that means they're using a cautery to burn through this mesh, okay. That is mesh, just like the analogous to the rebar, okay, rebar in concrete, okay. You got to get that out of there. It's a train wreck. You have to use a jackhammer to get it out. Obviously, in the human body you don't have to use that, but it's stuck in there because this is caked in scar.
MR. ISMAIL: I'm sorry. Move to strike, hearsay, 403, nonresponsive.
BY MR. SLATER:

Q. Is the mesh soft when it's coming out when you're taking it out from these complications, or does it have -- what does it feel like?
A. It's encased in scar, you can feel it. If you want to say a nice thing about mesh is when you can feel it, because it's firm in there, okay. Normal human body, it's not firm, okay. And so when you try and get rid of autologous slings, they're very actually difficult to find, but the meshes you can rub back and forth, I tell the residents, I say, feel right here because a lot of times we're working deep down in the pelvis. We can't see it. You have to go by proprioception, feel this, feel this band, feel where this is going through the obturator foramen. So, no, it's not soft at all.
Q. Let's go to Page 529 of this article, and in the left-hand column, the second full paragraph, I want to read a sentence, a short portion of it, and ask you a question. "One of our most important findings is that only 14% of patients were referred by the original surgeon, which suggests a lack of awareness of these complications by the original treating physician and the potential for underreporting of the rate and extent of these complications due to nonrespondent/volunteer

bias."
Is that significant to you?
MR. ISMAIL: Objection, hearsay.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Why?
A. This mirrors my practice. Let's just focus on this data here, but the majority, especially in here, of these patients are not being referred by their doctor back home. Their doctor back home is unaware of the level and the severity of the complication, and the patient is seeking care elsewhere, which, again, that mirrors my practice.
MR. ISMAIL: Again, I assume we have a standing objection on Plaintiff Exhibit 67 use of hearsay.
MR. SLATER: You have your standing hearsay objection.
MR. ISMAIL: Thank you.
BY MR. SLATER:
Q. Let's go to the top of page -- of the right hand column on Page 529, about four lines down. I want to read the sentence and ask you a question or two sentences.

Page 94

With the growing popularity of mesh insertion kits, in which a large surface area of synthetic material is placed, the vaginal surgeon is faced with the challenges of very complex surgical dissections. If mesh excision is warranted, tissue fibrosis, scarring, bleeding, and urinary tract and anorectal injury are easily encountered, which add to patient morbidity.

Is that of significance to you?

A. Yes.

Q. Why?

A. Well, that mirrors my weekly practice. This is complicated surgery. You have arguably three of the top urogynecologists in the nation, there's going to be others who are good, but these are top notch guys, highly experienced at a high volume tertiary care center, and they're saying they struggle to do this. I struggle when I'm getting these things out. It's a bear.

Q. Let's go to the bottom of that column, the right-hand column on Page 529. I want to read a sentence and ask you a question.

"It is important to remember that a percentage of patients who undergo pelvic reconstructive surgery

Page 95

with vaginally placed mesh will have life-changing complications. Moreover, whereas minor complications such as small vaginal mesh erosions are simple and easy to manage, incapacitating pelvic pain, dyspareunia, and large-scare erosions can be exceedingly complex and not easily resolved."

Is that significant to you?

A. Yes, it is.

Q. Why is that?

A. Well, again, there's a focus on the vaginal extrusion, which the data from other individuals would say that is a much more recurrent problem than we knew at this point in time, but we're saying these are some life-changing, severe, life-altering problems that occurs as a result of the Prolift® mesh.

Q. And this article, the description of these various complications, in your opinion, do they apply to the Prolift®?

A. Absolutely.

Q. I want to go to the bottom of the first full paragraph on Page 530, the last sentence. This was February 2009, correct?

A. Correct.

Page 96

Q. "The widespread marketing of these technologies should be avoided until level I evidence becomes available demonstrating their superiority over traditional repairs, with acceptable rates of morbidity."

Is that significant to you?

A. Yes, it is.

Q. And why is that?

A. They're stating here that basically this product is out without high quality studies showing that it's worked and it's safe, and they're saying it should not have been accepted, it should not be performed.

Q. With regard to the Prolift®, do you have an opinion as to whether what I just read is accurate?

A. It is accurate, yes, I support it completely.

Q. Did they -- did Ethicon have level I evidence demonstrating superiority of the Prolift® over traditional repairs with acceptable rates of morbidity before it was marketed, in your opinion?

A. There were no studies, no.

Q. Did such studies ever exist, in your opinion, level I evidence showing the superiority of

Page 97

the Prolift® over traditional repairs with acceptable rates of morbidity, was that ever produced for the Prolift®?

A. No. There are studies out there showing efficacy, anatomical success, but we've already talked about that. That's not quality of life. So to answer your question specifically, no, that has not been done.

Q. Let's go to the next PowerPoint slide.

Doctor, I want to ask you about testimony from David Robinson where he testified that gynecology had not adopted the routine use of meshes due to unacceptably high mesh complication rates.

Are you familiar with that testimony?

A. Yes, I am --

MR. ISMAIL: Objection, argumentative, lack of foundation.

BY MR. SLATER:

Q. David Robinson, who was the medical affairs director, listed what he perceived to be unacceptably high mesh complication rates, 6 to 25%, 3 to 12% and 6 to 12% from various studies.

Are you familiar with that?

A. Yes.

MR. ISMAIL: Sorry. Objection to the use

Page 98

of the slide, 403, argumentative.
BY MR. SLATER:
Q. With regard to the use, the routine use of meshes and the nature of the complications one sees with the Prolift®, do you agree or disagree with the medical affairs director that these types -- these rates of complications with the Prolift® whether that would be acceptable or unacceptable?
MR. ISMAIL: Same objection.
BY MR. SLATER:
Q. You can answer.
A. I have yet to answer any of the questions yet.
Q. You can answer.
A. Yes, I am familiar with this document, these are the depositions which I read, so I am very familiar with this, and I agree with him that the -- it has not been accepted due to high complication rates, and these are the numbers that he quoted.
Q. Let's go to the next slide.
Doctor, we have a PowerPoint slide here entitled "Prolift® TVM Complication Rates."
What is this showing us?
MR. ISMAIL: Objection, hearsay.

Page 99

THE WITNESS: These are multiple different studies, I reviewed all of these studies.
They're listed here. There are some --
BY MR. SLATER:
Q. Let me ask you -- let me stop you. These studies, are these studies medically reliable and authoritative in the field?
A. Yes, these are good quality studies.
Q. And did you rely on them for forming your opinions in this case?
A. Yes, I did.
Q. Okay. Go ahead, tell us what we're seeing here.
MR. ISMAIL: Objection, hearsay.
THE WITNESS: Basically, these are a combination of all the complications reported in these various different studies from these various different surgeons, going from as low of 15.6 to up to 33.6.
BY MR. SLATER:
Q. Now let's go to the next slide. Where we have side by side the rates of complications David Robinson had described as unacceptable versus the rates of complications for various studies of the Prolift®.

Page 100

Why did you want to have this slide put together comparing these rates?
MR. ISMAIL: Objection, hearsay to slides 15 and 16.
THE WITNESS: I put them in here specifically because David Robinson, a person of authority within Ethicon, had stated various different unacceptable rates as listed there from 3% up to 25%, as it states, and then we compare it to the available literature of these selected articles of stating complication rates much higher than that.
BY MR. SLATER:
Q. Do you have an opinion when you look at the rates of complications for these various studies of the Prolift® whether or not those rates are acceptable from a medical safety standpoint or not, in your opinion?
A. From my opinion, based upon my daily experience or weekly experience with these individuals is that each one of those complications represent a human being's life who has potentially been devastated, so these are unacceptable rates.
Q. And do you base your opinion also on your

Page 101

reading of that literature and other associated literature?
A. These are just six to eight selected articles. There's many more articles -- and that's also not including my attendance at national, international meetings about this exact subject or -- and lecturing on them.
MR. ISMAIL: Objection, move to strike, hearsay.
BY MR. SLATER:
Q. Let's go to the next exhibit, take the PowerPoint down. PLT0108, the next exhibit.
Doctor, I provided you Exhibit PLT0108. This is an article by various doctors, including Dr. Cosson.
Is this an article that you have relied on for your opinions?
A. Yes, I have.
Q. And is this article, in your opinion, medically reliable and authoritative?
A. Yes, it is.
Q. And this was dated as an accepted date of July 25, 2005, just a few months after the Prolift® went on the market?
A. Correct.

Page 102

Q. And, again, Cosson, he's the one who was named in the final study report for the TVM study, he was the lead investigator for the Prolift® prototype study?
A. That is correct, yes.
Q. If we look in the abstract section in the beginning, about halfway down that abstract, they say that 34 cases of mesh exposure were observed within the two months following surgery, which represents an incidence of 12.27%.
Do you see that?
A. Yes, I do.
MR. ISMAIL: Objection, hearsay, standing objection to 108, please.
MR. SLATER: Yeah, you have a standing objection to them all.
MR. ISMAIL: I know, but I feel like I have to identify which ones are the inappropriate hearsay for the record.
MR. SLATER: No problem. You don't have to object again to this article.
THE WITNESS: Yes, I do, I see that.
BY MR. SLATER:
Q. Now, what I'd like to do is turn to the

Page 103

last page -- before I do that, just for the record, you may have talked about it before, what is mesh exposure?
A. Mesh exposure, I have to be very careful on the nomenclature, good you point that out, mesh exposure now is defined as mesh that's coming through the vagina. If you look back at older report, they may talk about mesh erosion. Now mesh erosion is reserved for when mesh is eroding into another organ, bladder, rectum or somewhere else.
Q. That's a strict definition you apply in your clinical and academic practice, correct?
A. That is correct, yes.
Q. Do people still interchangeably use those terms?
A. Routinely the terms are used interchangeably, but in academic presentations and in papers now, it's very well-defined.
Q. Looking at the last page, the conclusion to the article written by -- the last author listed is the senior author, that would be Cosson, right?
A. Correct.
Q. Looking at the conclusion, the last paragraph, I want to read something and ask you a question about it.

Page 104

"Nowadays, based on these data, we can only advise that caution be exercised when carrying out this new surgical procedure. In fact, experimental studies and clinical trials seem necessary in order to reduce the level of exposure to less than 5% of cases."
Is that statement of significance to you?
A. Very much so, yes.
Q. Why is that?
A. Well, because you have one of the highest -- at this point in time, one of the highest volume surgeons, Dr. Cosson, who is involved in the original studies of this, who knows it probably better than most -- well, much greater than most surgeons, and he, in his opinion, is saying that we have -- are having basically an unacceptably high complication rate. This should be reserved as an experimental procedure, meaning not widely accepted, until we can get that exposure rate down to he says 5%.
Q. Was the exposure rate across the board in general in the medical community, when you look at the medical literature, ever brought below 5% for the Prolift®?
MR. ISMAIL: Objection, hearsay.
THE WITNESS: No.

Page 105

BY MR. SLATER:
Q. We had gone through an exhibit just a few minutes ago listing exposure rates for various Prolift® studies. Were they below or above 5%?
MR. ISMAIL: Objection, hearsay.
THE WITNESS: All those are above, and any studies I've ever reviewed which hint at lower, they're always short-term studies.
BY MR. SLATER:
Q. Let's go to the next exhibit.
Doctor, I've handed you what we've marked as Exhibit PLT0011. It's an a ACOG Practice Bulletin with regard to Clinical Management Guidelines for Obstetricians-Gynecologists, February 2007, and it says in the left column it was authored with the assistance of Dr. Scott Smilen and Dr. Anne Weber.
Are you familiar with this document?
A. Yes, I am.
Q. Is this something you've relied on for your opinions?
A. Yes, I have.
Q. Do you find this to be medically reliable and authoritative in the field?
A. Yes.

Page 106

Q. I want to now draw your attention in this practice guideline, this is just -- these are recommendations to gynecologists in day-to-day practice for things they should consider and how they should practice routinely?

A. Correct. It's a bulletin that ACOG, which is the American College of OB-GYN puts out periodically on a routine basis of just updates for people to get a synopsis of what's going on.

Q. If you look at Page 468, the top right-hand portion, the last -- the first full paragraph in the right column, I'm going to read it and ask you a question.

MR. ISMAIL: Before do you, standing objection as hearsay to Exhibit -- Plaintiff Exhibit 11.

MR. SLATER: You have a standing or a sitting objection.

MR. ISMAIL: Thank you.

BY MR. SLATER:

Q. I'm going to read the first full paragraph in the right-hand column on Page 468.

"Given the limited data and frequent changes in the marketed products (particularly with regard to type

Page 107

of mesh material itself, which is most closely associated with several of the postoperative risks, especially mesh erosion), the procedures should be considered experimental and patients should consent to surgery with that understanding."

Is that significant to you?

A. Yes.

Q. And why is that?

A. That this -- the ACOG board following review of the literature, has come with the opinion that the procedure is experimental, which means it should not be used in widespread for every patient.

Q. Do you have an opinion as to whether or not the Prolift® should or should not have been considered and actually utilized as an experimental procedure?

MR. ISMAIL: Objection, cumulative.

THE WITNESS: I have an opinion and it should have stayed as an experimental.

BY MR. SLATER:

Q. When something is experimental, what does that mean?

A. Experimental puts it in a completely different class of surgeries. The standard anterior

Page 108

colporrhaphy, the traditional repair is not experimental. A procedure that is experimental means that it has not been proven safe and efficacious. It has to be both, can't just be one or the other, and so until it is proven safe, it cannot be for every surgeon to be doing it. It has to be under very close study guidelines with a highly informed and consented patient.

Q. Are you familiar with the fact that later in 2007, ACOG modified the bulletin to remove the word experimental?

A. Yes, I read that.

Q. Do you know why that was done?

MR. ISMAIL: Objection, first, relevance, 403, lack of foundation.

THE WITNESS: I have read the internal documentation e-mails of how that came about, yes.

BY MR. SLATER:

Q. In very simple terms, what happened?

MR. ISMAIL: Same objection, also improper expert testimony, doesn't aid the jury.

THE WITNESS: There was pressure put on the ACOG bulletin, the committee that does

Page 109

this, by individuals paid by Ethicon to change -- get rid of the experimental.

BY MR. SLATER:

Q. Do you have an opinion as to whether or not the word experimental should have remained in that bulletin or not?

MR. ISMAIL: Same objections.

THE WITNESS: Absolutely should have.

BY MR. SLATER:

Q. Should have remained?

A. Should have remain -- absolutely, it should have remained there as experimental.

Q. Let me ask you a question, we just saw an ACOG bulletin in February 2007 saying that these mesh kit procedures should be experimental.

Is that the same thing that Cosson, the developer of the procedure, said in 2005?

MR. ISMAIL: Objection, leading.

THE WITNESS: That is what he stated, yes.

BY MR. SLATER:

Q. Let's go to the next exhibit, and it is an article that we've marked as PLT0139.

Is this an article that you are familiar with?

A. Yes, sir.

Page 110

Q. Is this an article that you believe to be medically reliable and authoritative?
A. Yes, as it pertains to the abstract. The remainder of the article is in French, so I have read it and I can (speaking in French), I can read a bit, but I can't read in detail here.
Q. With regard to the English abstract on the second page, is that medically reliable and authoritative?
A. Yes.
Q. And that's something you relied on for your opinions?
A. Definitely, yes.
Q. And this was written by various doctors from the TVM group, including Cosson?
A. Yes.
Q. And let's look at the abstract, let's look at the summary of the study they did?
MR. ISMAIL: Standing objection, hearsay, Plaintiff Exhibit 139.
MR. SLATER: Standing objection.
MR. ISMAIL: Thank you.
BY MR. SLATER:
Q. And what I want to do is go through this

Page 111

in the first sentence, actually, the second sentence, it says, "In light of the growing number of proposed techniques and materials we reviewed the experience of the pioneers in order to provide surgeons with the most objective information available," and they're talking about the use of transvaginal mesh?
A. Correct.
Q. In the body of the article, they talk about certain complication rates with the use of synthetic mesh to treat prolapse, and about halfway down it says, "The rate of erosion was also quite variable, as high as 45%," and then two lines down it says, "the rate of dyspareunia has reached as high as 60%. Here again grades of prosthetic retraction should be better defined."
So stopping there, is that information significant to you?
A. Yes, it is.
Q. Why is that?
A. Well, they're reviewing, you know, all the synthetic meshes around, saying there's a high rate of complication specifically when they're talking about the retraction.
Q. The next -- rephrase.

Page 112

In the middle of the section of the summary it says, "Proposed to improve these phenomena, soft Prolene recently used by several authors does not appear to fulfill expectations."
Is that significant to you?
A. Yes, it does.
Q. Why is that?
A. Because you have to look at, you know, that's why I mentioned the first part of this. They're talking about the historical things, the Marlexes and the Gortexes and the complication rates that were found with those; therefore, individuals said, let's use a different mesh. Let's use Prolene soft, okay. And then when they did that, and, again, this is the early days, these are the highest volume surgeons probably in the world at that time, and they said the Prolene soft did not meet -- reach the expectations they had hoped it would.
Q. And when they talk about the authors, that includes Cosson, who developed the Prolift®?
A. Yes, Cosson, among others, yes.
Q. And soft Prolene, just to be clear, that's the mesh in the Prolift®?
A. Correct.

Page 113

Q. Go down towards the bottom, the last paragraph, and it says in part, "The lack of data on the rate of complications and patient quality of life is unacceptable for this functional surgery. We still have reservations about widespread use of synthetic meshes."
Is that significant to you?
A. Yes, very much so.
Q. Why?
A. Okay. Again, that's what I've been stating all along. This is a quality of life problem, okay. And these surgeons when they say functional, that means quality of life. And so they address what I already mentioned multiple times.
Q. Let's go to the next exhibit PLT0696.
Doctor, Exhibit 0696, PLT0696, is an article titled "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study" by Dr. Abbott, et al.
Are you familiar with this article?
A. Yes, I am, very much so.
Q. And is this article medically reliable and authoritative in the field, in your opinion?
A. It's a very good article, yes.

Page 114

Q. Is this an article you've relied on in forming your opinions?
A. Yes, I have.
Q. What I would like to do first is turn to -- well, rephrase.
Very simply, what is this article about; what are they talking about?
MR. ISMAIL: Objection, hearsay, Exhibit 696, standing objection.
MR. SLATER: Yep.
BY MR. SLATER:
Q. Let me ask the question again. What is this article about? Let's start in general, and then we'll go to specifics real quick.
A. The article, as it states, which is important, it's a multicenter study, so it's not just one institution. So it's experience of multiple different doctors, high volume, high profile, top notch surgeons, and they're evaluating the -- their complications that they have seen and referred in to their institution from meshes and then the outcome following these. So it's much more advanced study than the original Blandon one. Blandon one is early is. This is now late with multiple studies looking at this

Page 115

problem.
Q. The concepts that we're going to talk about in this article, do they apply to the Prolift®, in your opinion?
A. Yes.
Q. Okay. Let's first turn to Page e3, and there's a Table 2.
Do you see that?
A. Yes, I do.
Q. And first at the top it says, there were 347 patients?
A. Correct.
Q. And if you go down further it says, "smoking status." What is that telling us?
A. As it states, did the patient smoke, have they never smoked, past smoker or a lifetime nonsmoker.
Q. And what was the statistics on the 347 patients?
A. Well, just reading it right off of there, never smoked was 61%, past smoker 21%, current smoker was 12.4%.
Q. And with regard to the concept of mesh erosion and complications that are discussed in this article, and we're going to get to them in a second,

Page 116

what does this tell us about whether smoking, in your opinion, factors into that?
A. Well, it's not just my opinion, but the opinion of these authors that smoking was not a factor because if you look at never smoked, 61%. If you add in there the previous but current nonsmokers, that equals a total of 82% nonsmokers. So 82% of the people weren't currently smoking and they had complications.
Q. Let's go to page e5, if we could. And what I would like to do is draw your attention to the middle column, and the first full paragraph, about halfway down, and they're talking about the patients and some statistics on them, and it says, the most common complaints were mesh erosion (42.7%), pelvic pain (34.6%), and dyspareunia (30%), although most women (70.3%) had with greater than one distinct symptom or complaint.
What is significant, if anything, about that?
A. It means you have, to be basic, a bunch of problems to fix. 70% were coming in with more than just one problem, and then it breaks it down what those various different problems are, but, I mean, it's not just one thing you have to try and fix.
Q. Turn to the next page, the Comment

Page 117

section, please, Page e6, and it says a little down from the beginning of the comment section, approximately one half of the women who sought treatment of a mesh-related complication at a tertiary referral center actually underwent their index procedure, or their first procedure, at another facility. This trend has been reported in other studies as well. This raises the potential concern that physicians who perform these mesh procedures may not be aware of the complications their patients experience and that these providers may be responsible for future mesh-related complications, with no awareness of the existing magnitude of the issue.
Is that significant to you?
A. Yes, it is.
Q. Why is that?
A. Well, for two different reasons. Number one, 50% of the procedures -- let's break it up into 50/50. 50% of these procedures, these complications they're facing were done by high volume, high qualified surgeons, okay, so that raises a problem right there.
Number two, the other 50% were done by surgeons who are unaware that this complication is even existing, so it's multiple problems with that statement

Page 118

right there.
Q. Let's look at the right-hand column on page e6, almost halfway down the page, there's a sentence that starts, "Furthermore, complications after TVM tend to be more severe, are more chronic in nature and can be more difficult to treat. For instance, mesh erosion, pelvic pain, dyspareunia, vaginal constriction, vaginal spotting and obstructive defecation were all significantly more common after index surgery with TVM than 1 with sling only."
Is that significant to you?
A. Oh, absolutely. They're describing here that this is a problem that we can't fix. In medical school, residency and advanced training, we are trained to fix problems. That's what doctors are supposed to do, and they're stating we can't fix it.
Q. Let's go down further on the third column on Page e6, almost to the bottom, about eight lines up, it says, "Most patients (60%) received 2 or more unique interventions; even then, there was no guarantee of symptom resolution."
What, if any, significance is that?
A. Okay. It's that there used to be this dogma of oh, treat a mesh exposure, that's it, it's

Page 119

gone, no big deal.
What they're saying is it requires multiple -- 60% of their patients required two or more, and I think later on they say there's something like 12% required up to five or six, so it's a much larger number. I don't have any specifics right here. So but bottom line, it's a problem that continues to create more problems, and it can't just be resolved quickly.
Q. The description of complications and the issues with treating the complications in this article, in your opinion, do these concepts apply to the Prolift®?
A. Absolutely, yes.
Q. Do you have an opinion as to whether or not this profile of complications is medically safe or unsafe for patients?
MR. ISMAIL: Objection, cumulative.
BY MR. SLATER:
Q. What's your opinion?
A. It's unsafe.
Q. Let's go to the next exhibit, which is PLT1095, which I did give you before.
MR. ISMAIL: When we came in first thing the morning?

Page 120

MR. SLATER: Yes.
MR. ISMAIL: Thank you.
BY MR. SLATER:
Q. Doctor, Exhibit PLT1095 is an article titled "Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh." There's a few authors, including -- is it Heesakkers?
A. John Heesakkers.
Q. Heesakkers and Mariëlla Withagen from 2011.
Are you familiar with this article?
A. Yes, I am.
Q. Is this article medically reliable and authoritative in the field, in your opinion?
A. Yes, it is.
Q. Is this an article you relied on?
A. Yes.
Q. And do you know any of these authors?
A. I've heard Withagen speak. John Heesakkers, he is the chair of the European Urology Reconstructive Surgery, which I am a board member of, so I've talked to him, I've talked to him about mesh complications, so I know him personally.

Page 121

Q. Let's turn -- this is a paper about the treatment of mesh complications, including Prolift®?
A. That's correct.
MR. ISMAIL: Objection to hearsay, Exhibit 1095, also, on not disclosed previously as a reliance material for this witness.
Standing objection?
MR. SLATER: Standing objection.
MR. ISMAIL: Thank you.
BY MR. SLATER:
Q. Let's turn to the fourth page, Page 1398, and first I want to read something in the right-hand column. About halfway down the right-hand column it says, a distinct difference in frequency of mesh-related symptoms existed between the different types of mesh insertion procedure, especially in sacrocolpopexy compared to the other procedures. Pain and dyspareunia are mainly seen after mesh insertion and vaginal bleeding and discharge after sacrocolpopexy.
Is that significant to you?
A. Yes.
Q. Why is that?
A. Because then they're going back to this

Page 122

issue of this being a quality of life problem and this patient having with the mesh kits, transvaginal mesh kits having the vaginal pain.

Q. I'm going to ask you to do something. Can you just grab the mesh from the anterior kit real quick.

With the abdominal sacrocolpopexy, is mesh used, where it's put in through the abdomen?

A. Yes, through the abdomen, which is different than through the vagina.

Q. And can you illustrate for the jury holding up the Prolift® how much mesh would be used in a abdominal sacrocolpopexy and give the jury some idea of the difference.

A. Well, you have to break it down so we can see it here. So this is the mesh for the anterior prolapse, anterior Prolift® and then the --

Q. Hold it up more.

A. The amount in contact with the vagina, we're not talking about the arms, just the vagina is going to be this part here, okay. And then you also have the arms, okay, which go through the muscles what I've already referred to.

Now, for the sacrocolpopexy, the robotic

Page 123

sacrocolpopexy or the open procedure, the amount in contact with the vagina is going to be about that much, okay, maybe a little bit more, maybe a little bit less, and you'll be able to have it lie flat anteriorly, and there may be also a piece that size going posteriorly. In direct contact with the vagina is significantly less.

Q. That size difference, what's the size of the amount of mesh, can you estimate the size of what's used with the abdominal procedure?

A. Okay. It's going to be anteriorly, what's that, 2, maybe 3 centimeters, and also what I do is, and most people do, is you trim the top so it's a little more curved so it would actually be less than this. Let's just say 2 by 2 anteriorly, posteriorly maybe 2 by 3 centimeters, which is going to be significantly less, you can just visualize it, significantly less than the volume of mesh put in otherwise for the Prolift®.

Q. So that's about an inch, 2 centimeters?

A. 2.54 centimeters in an inch.

Q. So a little less.

A. That's why I just said, just look at this.

Q. Okay. Do you have an opinion as within --

Page 124

as between abdominal sacrocolpopexy and the Prolift® procedure as to which one has a more or less acceptable safety and efficacy profile overall?

MR. ISMAIL: Objection, cumulative.

THE WITNESS: Yeah, the data will show the abdominal sacrocolpopexy, whether it be done robotically, laparoscopically or with an incision is a much safer procedure, with lower incidence of dyspareunia, chronic problems associated with Prolift®. So it's a -- you can't compare the two. They're apples and oranges as far as the procedure goes.

BY MR. SLATER:

Q. Let's turn now to Page 1402 of the article that we are discussing here. The Heesakkers-Withagen article and in the right-hand column, towards the top right, top paragraph, last sentence, it says, also, the urologist is always involved in the treatment of patients with (suspected) mesh complications affecting the bladder.

Is that significant to you?

A. Yes.

Q. Why is that?

A. Because what Withagen, who's a, you know,

Page 125

highly trained, very good pelvic surgeon is what she's saying, and she gets another expert involved in the bladder, because these are so difficult to get out.

Q. Let's go down further in that column to the last -- the second to last -- really, the last full paragraph and about halfway down through that it says, "Of the patients included in this study, 20 underwent insertion of Prolift® at our hospital between halfway of 2005 and end of 2009. In this period, 180 Prolift® meshes were inserted. So, 20 out of 180, (11%) patients with Prolift® inserted at our center developed complications that required excision."

Is that significant to you?

A. Yes, it is, especially given the probably relatively short amount of follow-ups, that's a very high number.

Q. Having over 10% reoperations to remove mesh?

A. It's quite -- that's a very high number, yes.

Q. Finally, I want to go to the last page of the text. The Conclusion, the very bottom of the left column over to the top, I want to read something and ask you a question. So we're at the bottom of the left

Page 126

column under the Conclusion, the last paragraph.
A. I'm there.
Q. It says, "The increasing number of inserted meshes for SUI and POP raises concerns. Mesh is successfully used for repair of prolapse, but when complications arise, they may be severe in nature and result in a decrease in quality of life. New meshes are introduced into clinical practice, despite the lack of proper studies showing their safety and effectiveness. Moreover, the use of easy-to-do mesh kits lowers the threshold for inexperienced surgeons to start operating with meshes. This can only lead to more complications, which is harmful for the patients."
Is that significant to you?
A. Very much so, yes.
Q. Why is that?
A. Well, you go point by point through here is -- in the first line, mesh is successfully used to repair prolapse. You know, I agree with that, that they can repair prolapses. Now we had a high failure rate, it's 20% or so, but that's not the issue. It's that these complications are the problem. That's the life-changing aspect of it and that they're introduced without any studies, okay. There were no human studies

Page 127

on Prolift® prior to release, okay. To my opinion that is unethical and unacceptable.
And then, number three, this gets into more of a discussion, these easy kits allow inexperienced to start -- inexperienced surgeon, to allow them to operate, that's beyond the scope of this here. But it raises the ability for people who are not advanced surgeons of doing these things. Again, that's, to a certain degree, a different issue here.
MR. ISMAIL: In addition to hearsay, which has been preserved, move to strike as nonresponsive and not proper grounds for expert testimony.
BY MR. SLATER:
Q. Let's go to the next exhibit.
Doctor, I've handed you what we've marked as Exhibit -- actually, what number is on that?
A. P2731.
Q. Is it P or PLT?
A. P.
Q. Just P, okay. Okay. Let me start over.
Doctor, I've handed you Exhibit P2731, and this is a page from the New England Journal of Medicine?
A. That is correct.

Page 128

Q. And in the bottom right-hand column there's a set of corrections.
Do you see that?
A. Yes, I do.
Q. And the bottom one says that there was a correction to an article titled "Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic Organ Prolapse," published in the New England Journal of Medicine, May 12, 2011.
And are you familiar with that article?
MR. ISMAIL: Objection, hearsay.
THE WITNESS: Yes, I am, the Altman study, I'm familiar.
BY MR. SLATER:
Q. And they talk about a correction that was made to some language in the Altman study of the Prolift®?
A. That is correct.
MR. ISMAIL: Objection, hearsay.
Standing objection 2731.
BY MR. SLATER:
Q. If somebody in this courtroom were to have relied on the Altman study to say that that is proof of the safety or efficacy or that the Prolift® is a

Page 129

suitable device or system, what would be your response to that based on the correction and the information you have available to you from the depositions of the editors of the New England Journal of Medicine and the internal documents you've seen from the company?
MR. ISMAIL: Objection, hearsay, 403.
BY MR. SLATER:
Q. You can answer.
A. Based upon what I have read, as you mentioned, the depositions from the journal -- New England Journal of Medicine editors, what I've read of internal documentation, of correspondence going back and forth between the author and key people, three or four within Ethicon, that the author originally stated that this data was not -- had no industry involvement. And then we come to find out that roughly, what, 100 or so changes were made by Ethicon on this document.
Subsequently, there's no disclosure of bias, which is the reason why rules exist is to declare if there's a potential bias. So that Altman study, along with other errors that were pointed out on POP-Q scores makes that study unreliable and false.
Q. When you talk about errors with POP-Q scores, what are you talking about, and why is that

Page 130

significant in assessing the validity of the Altman study?
MR. ISMAIL: Objection, 403, hearsay.
THE WITNESS: POP-Q is a grading system, POP-Q, pelvic organ prolapse quantification of the prolapse, okay. It's basic numbers and certain POP-Q scores, we should abbreviate POP-Q, because it's just easier. It's a very logical system, and so in my review of these internal documents, e-mails back and forth and depositions, we find out that those POP-Q scores are not possible, not physically possible, so, therefore, that data is false. That's why I have been privy to information the average doctor on the street has not been. So, again that's why it's a major because it undermines the very core and validity of that information.
MR. ISMAIL: Objection, move to strike, nonresponsive.
BY MR. SLATER:
Q. Let's go to the next PowerPoint slide.
Doctor, I want to ask you about some characteristics of the Prolift® and ask you a question

Page 131

about them, okay?
A. Okay.
Q. First of all, did you compile a list of what you believe to be medically unsafe Prolift® characteristics?
A. Yes, in an abbreviated form listed here, yes.
Q. The first one, "tension is unavoidable/no 'tension free'"
MR. ISMAIL: Object to the -- sorry.
BY MR. SLATER:
Q. You've talked about these things, some of them at length, but I just want you to briefly just tell us why you include that in the list?
MR. ISMAIL: Object to the slide as argumentative, object to the testimony as cumulative.
THE WITNESS: Tension free is not physically possible within the female pelvis. So that's why it's tension free is -- tension is going to happen, which then goes down to one of the root sources of problems, where you get tension, you get the pore size collapse, then you cause that inflammation, foreign body

Page 132

reaction, scarring and pain.
BY MR. SLATER:
Q. Number 2, mesh does not lay flat in an unstretched condition.
Why do you say that?
MR. ISMAIL: Objection, cumulative.
THE WITNESS: As I stated earlier, you can't get that mesh to lie flat. If it doesn't lie flat, it bunches, it curls, ropes and then that causes, again, that cascade of the problem, pore size decrease, foreign body reaction, inflammation, pain.
BY MR. SLATER:
Q. With regard to the arms, roping, curling and banding, location in obturator space and deep pelvis, why do you include that?
MR. ISMAIL: Objection, cumulative.
THE WITNESS: The roping, curling and banding, we showed multiple times here, that's going to cause that -- those arms to roll up, scar. They band, you can feel them on physical exam. Going through the obturator foramen space and deep pelvis, the significance of that is it's going to anchor it in and those

Page 133

muscles, those multiple muscles that have been pierced will then contract with pain -- excuse me -- with activity causing pain.
BY MR. SLATER:
Q. Mesh does not incorporate safely in the pelvis.
What does that mean?
MR. ISMAIL: Objection, cumulative.
THE WITNESS: That's what we've been stating multiple times. This mesh is not a safe product to be placed in the female pelvis transvaginally.
BY MR. SLATER:
Q. Difficult/impossible to safely and effectively remove the mesh.
Why do you say that?
MR. ISMAIL: Objection, cumulative.
THE WITNESS: Because the product when put in for a quality of life issue, it is impossible to get that mesh out completely. You can leave behind or do severe damage to the pelvic structures in trying to take it out.
BY MR. SLATER:
Q. Do you hold those opinions to a reasonable

Page 134

degree of medical certainty?
A. Yes, those are based upon my personal experience, review of the literature, internal documentations, everything.
Q. Based upon the list of medically unsafe Prolift® characteristics that you have compiled, do you have an opinion as to whether or not the Prolift® system is a defective -- defectively designed system and procedure for the treatment of pelvic organ prolapse?
MR. ISMAIL: Objection, cumulative, lack of foundation, lack of qualifications.
THE WITNESS: As I've mentioned, based upon my experience in taking care of these complications, my experience performing the traditional repairs without mesh, that this was an unsafe, poorly designed product that has no role being placed in the female pelvis.
BY MR. SLATER:
Q. Let's go to the next slide.
Doctor, did you compile a list of injuries caused by medically unsafe Prolift® characteristics, meaning what the consequences are of the list of characteristics you listed on the prior slide?

Page 135

MR. ISMAIL: Objection. Sorry. Objection, the slide is argumentative, also 403 as being -- many of these being irrelevant to the plaintiff at issue.
MR. SLATER: I'm going to ask the question differently.
BY MR. SLATER:
Q. Doctor, I'd like to talk about a list of injuries caused by medically unsafe Prolift® characteristics, a list that we have here to talk through, okay?
A. Okay.
Q. Is this list applicable to the Prolift® in those issues that you just went through on the prior slide?
MR. ISMAIL: Same objection.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Doctor, I'm going to walk through these one at a time.
Chronic, severe inflammation, why is that, in your opinion, a result of a medically unsafe characteristic of the Prolift®?
MR. ISMAIL: Objection, 403.

Page 136

THE WITNESS: Because you're treating a quality of life problem, prolapse, and if you place a device in there that has chronic, severe, permanent and progressive inflammation, it's unacceptable to trade a quality of life problem with a viable, acceptable alternative and trade it for a chronic, permanent problem.
BY MR. SLATER:
Q. Contraction of the mesh, and then you have the term excessive. Tell us what that means and why that is, in your opinion, applicable?
MR. ISMAIL: Objection, 403, cumulative.
THE WITNESS: The key with that is, number one, contraction, so the mesh shrinks down as a result of the scarring and inflammation, but then excessive, so it's pulling on the muscles, causing the pain, causing banding, rolling and subsequently causing mesh exposure, so it causes multiple different problems.
BY MR. SLATER:
Q. Scar plating and fibrotic bridging, explain that, why that is a result of the Prolift®?
MR. ISMAIL: Objection, 403, cumulative.
BY MR. SLATER:

Page 137

Q. And what you've called medically unsafe Prolift® characteristics?
MR. ISMAIL: Cumulative.
BY MR. SLATER:
Q. Scar plating, fibrotic bridging, Number 3.
A. Thank you. Again, this goes back to the fundamental problem with the mesh of causing that plating. It doesn't cause tissue integration, where it goes through those pores. It causes that plating, which then causes the mesh to contract; bridging, which causes pain for both the partner -- excuse me -- for the patient in sexual activity with the partner also, along with other as far as just ambulation.
Q. Extrusion/exposure/erosion of mesh - complex/recurrent. What are you talking about there, and why is that an injury caused by a medically unsafe Prolift® characteristic?
MR. ISMAIL: Objection, 403, cumulative.
THE WITNESS: Due to the design of this product, what I see in my daily practice, because those pores constrict, because you get this fibrosis or persistent infection, you can get extrusion of the mesh, exposure, and the key here is complex and recurrent, meaning it's

Page 138

not just one quick little procedure and it's done. As that Abbott study showed it comes back multiple times.

MR. ISMAIL: Objection, move to strike, hearsay.

BY MR. SLATER:

Q. Vaginal pelvic pain, which can be chronic. Why is that the result of a medically unsafe Prolift® characteristic?

MR. ISMAIL: Objection, 403, cumulative.

THE WITNESS: This is one of the biggest issues which I see in my clinic on a weekly basis is that we now have a quality of life problem of this pelvic organ prolapse. Woman has fullness, pressure, and then now we've traded it for a chronic, progressive, permanent, unfixable problem, okay. So the women's quality of life, these are the patients that I have in my clinic, they and their spouse, they're crying because they are ruined because of a quality of life problem when there was a viable other option available.

MR. ISMAIL: Move to strike, nonresponsive.

Page 139

BY MR. SLATER:

Q. Dyspareunia, which can be chronic, why is that a result of a medically unsafe Prolift® characteristic?

MR. ISMAIL: Objection, cumulative.

THE WITNESS: That's just the same thing as what I just mentioned as far as with the vaginal pain, pelvic pain. Quality of life problem for permanent progressive problem is not fixable.

BY MR. SLATER:

Q. Pelvic floor myalgia, otherwise known as muscle spasms, which can be chronic, why does that result from medically unsafe Prolift® characteristics, in your opinion?

MR. ISMAIL: Objection, 403, cumulative.

THE WITNESS: This is due to those mesh arms going through all those muscles that I mentioned. When they pull, they tug, the pelvic musculature becomes irritated and painful, and so it's directly due to the presence of that foreign body and the arms in the product.

BY MR. SLATER:

Page 140

Q. Urinary dysfunction, which can be chronic, why is that a result of medically unsafe Prolift® characteristics, in your opinion?

MR. ISMAIL: Objection, 403, cumulative.

THE WITNESS: Okay. Due to the placement where this is placed, in the vesicovaginal space, in between the bladder and the vagina, where all the nerves for bladder function come in like this, you now have created that foreign body, which is going to cause contraction, erosion, inflammation, and it's going to affecting those nerves causing permanent bladder dysfunction, which you can't fix.

BY MR. SLATER:

Q. Mesh removal operations, why do you include that as injuries caused by medically unsafe Prolift® characteristics?

MR. ISMAIL: Objection, 403, cumulative.

THE WITNESS: Every surgery has risks to it, especially as the individual becomes older, there's data out there showing mentation issues, et cetera. So if the patient undergoes multiple surgeries to try and fix this, besides just the expense of it, the wear and tear on

Page 141

the human body, it's not just a one and done, easy fix, office procedure.

BY MR. SLATER:

Q. Doctor, you said earlier, and I'll just confirm it, you said you're familiar with the IFU for the Prolift®?

A. Yes, I am.

Q. This profile of injuries, complications that can be caused by the Prolift®, in your opinion, is that adequately warned of in any IFU for the Prolift® that you've ever seen?

MR. ISMAIL: Objection, lack of foundation, lack of qualifications.

THE WITNESS: No.

BY MR. SLATER:

Q. Is the medical information that is set forth in this list that you have compiled found in the Prolift® IFU, in your opinion?

MR. ISMAIL: Same objections.

THE WITNESS: No.

BY MR. SLATER:

Q. Is it important to not only warn of specific individual risks but also of the entire full spectrum of the risks at the same time?

Page 142

A. Yes.
Q. Why does that matter?
A. The IFU needs to warn about all the known complications, their severity, their frequency, so you got to -- and the ability to change it. So you've got to warn for all of those potential factors, which were all known.
MR. ISMAIL: Objection, move to strike under 705. Sorry.
BY MR. SLATER:
Q. Let me ask you this: Is it important for the entire risk profile and the most severe complications to be fully disclosed to the doctor?
A. Yes.
Q. Why is that?
MR. ISMAIL: Same objection.
THE WITNESS: The doctor, as a surgeon myself, I need to know so I can relay accurately to the patient, a human being that's sitting in my office, I have to be able to tell them, here's what we can expect, I have to be told all known complications, severity and their nature, what is known, so I can accurately consent my patient.

Page 143

BY MR. SLATER:
Q. Does that also enter into the risk-benefit analysis and what recommendations are made and how they're made?
A. Absolutely.
Q. Let's go to the next slide, "Treatment of Prolift® Complications."
Doctor, this list of treatment of Prolift® complications, I'll let you just walk through it and just quickly tell us, first of all, are these treatments that are known to be, in your opinion, to be necessary to treat various complications from a Prolift®?
MR. ISMAIL: Objection, cumulative and 403.
THE WITNESS: Many times, yes.
BY MR. SLATER:
Q. Okay. Just go through them one at a time. Tell us what you're specifically talking about and just tell us so we understand what they are.
A. Sure. I did not list the --
MR. ISMAIL: Objection. Sorry, doctor. I'll let you restart, but objection, cumulative and 403.

Page 144

THE WITNESS: I did not list these in level of complexity, which I probably should have, but starting off with mesh removal operation, this is to remove the mesh, that can be removal of an exposure, it's outpatient type procedure versus the complete removal of the mesh, which is a major transabdominal belly procedure, highly complicated thing. So that falls in the next point of just surgical care. These are complicated procedures requiring multiple office visits, multiple follow-up, multiple effect upon the individual's usual lifestyle, okay.
Pain management/injections, another option for treating pelvic pain. This is the majority of what I see. Unfortunately, I have yet to have, in my experience now, since meshes have come out, so now it's, what, ten years now, I have yet to have a successful pain management patient with meshes, I can't fix them. I have a physical therapy team. I have a nurse who works in biofeedback. I have an anesthesia pain clinic, can't fix them. So it's a permanent problem.

Page 145

Pelvic floor physical therapy, that's what I just mentioned, biofeedback, again, an option. I have had zero success.
Spinal --
Q. Let me just stop you there. Were you talking about success in terms of completely treating the condition and making the person completely better?
A. No. I'm talking about a significant reduction in their symptoms. I'm not -- I do not try to make -- let me back up.
I would love to be able to make someone pain free. I'm realistic, I can't. I am happy if I can get a significant reduction in their pain. I can't even get that, and I've got arguably some of the best people around to help me out, and I can't do it. I wish I could.
Q. Let's go on, spinal stimulator.
MR. ISMAIL: Objection, 403, cumulative.
THE WITNESS: The spinal stimulator evolved with our pain clinic. It's just another way of injecting pain medication to the spine or locally.
Catheterization is dealing for bladder dysfunction that occurs afterwards, where the

Page 146

woman is in retention and can't urinate because of contraction.

Medication is again going down the lines of bladder spasm medication or pain medication, which I allow my pain clinic colleagues to deal with that.

BY MR. SLATER:

Q. Okay. Let's go to the next PowerPoint slide. Doctor, I want to ask you about a statement made by David Robinson in his deposition of March 13, 2012, Page 52, Line 11 to 15 and ask you a question about it.

First of all, you read that deposition; you know this testimony?

A. Yes, I did.

Q. "Data should establish that the benefits far outweigh the risks before the product is sold for widespread use."

Did Ethicon ever establish data that would satisfy that criteria?

MR. ISMAIL: Objection to the use of the slide as argumentative, and testimony is cumulative, lack of foundation.

THE WITNESS: No.

Page 147

BY MR. SLATER:

Q. Do you have an opinion to a reasonable degree of medical certainty as to whether or not the overall risk-benefit profile for the Prolift® was medically acceptable?

MR. ISMAIL: Objection, cumulative.

THE WITNESS: It was not medically acceptable.

BY MR. SLATER:

Q. And is that for the reasons you've stated throughout your testimony?

MR. ISMAIL: Same objection.

THE WITNESS: Yes.

BY MR. SLATER:

Q. Let's go to the next PowerPoint slide. I want to ask you about some testimony that Ethicon medical affairs directors gave regarding the standards they described for what the warnings of risks needed to communicate.

Are you familiar with what that testimony was?

A. Yes, I've read all those depositions.

Q. And is that testimony something that you've relied on in forming your opinions?

A. Yes.

Page 148

Q. And do you agree with the descriptions of the criteria for what warnings needed to communicate regarding risks as testified to by the medical affairs directors; do you agree with that testimony?

MR. ISMAIL: Objection to the slide as 403 and argumentative and to the testimony as 403, argumentative and without qualification.

THE WITNESS: Yes, I agree to each of those five points I pointed out.

BY MR. SLATER:

Q. And just to be clear, Doctor, to meet any objection, in your practice, you have utilized and not only utilized but taught residents the use of the IFU, including risk information?

A. Oh, absolutely, yes.

Q. And, in your experience, is it necessary for you to understand how to read an IFU and literature from a manufacturer to determine how to use that risk information in treating patients?

A. Absolutely. I have to trust what I read on the IFU, so that's why I relay on to the patients and relay on to my residents during education.

Q. Let's go to the next exhibit, Exhibit P1005.

Page 149

Doctor, let me start over. Get a drink of water.

Doctor, looking at Exhibit P1005, this is an IFU that Ethicon has advised us was in effect from 2007 until, I believe, September 2009.

Are you familiar with this IFU?

A. Yes, I am.

Q. And you've talked about it before. You're familiar with the document and the various bits of information in there?

A. Yes.

Q. I want to just ask you to just run through a few things and ask you brief questions about them. Let's go to the second page. There is a heading halfway down just below the table that says "Gynecare Gynemesh® PS," and that's the name of the mesh material in the Prolift®?

A. That is correct.

Q. The last sentence of that section says, "The bi-directional elastic property allows adaptation to various stresses encountered in the body."

Are you familiar with that statement in this IFU?

A. Yes.

Page 150

Q. Have you in all the materials you've reviewed seen whether Ethicon had any data to support making that claim in the IFU?
A. They had none.
Q. Do you have an opinion as to whether or not it was appropriate or inappropriate for Ethicon to make that statement in the IFU?
MR. ISMAIL: Objection, improper expert testimony.
THE WITNESS: It would be inappropriate and misleading to the surgeon.
MR. ISMAIL: Move to strike, nonresponsive.
BY MR. SLATER:
Q. Based on your knowledge and experience and familiarity with the literature and the use of IFUs, do you have an opinion as to whether surgeons expect that the information in an IFU is accurate?
MR. ISMAIL: Objection, improper expert testimony.
THE WITNESS: You expect and I used to expect it to be honest and truthful.
BY MR. SLATER:
Q. What do you mean by used to?

Page 151

MR. ISMAIL: Objection, 403, improper testimony for an expert.
THE WITNESS: In my daily practice as a surgeon, and I had reviewed these, I had expected in the past to have it be an honest representation of what was known, so that I could relay honestly to my patients, people that I care for and am trained to care for, and now I do not believe that is true anymore.
MR. ISMAIL: Objection, move to strike.
BY MR. SLATER:
Q. Let's go to Page 5 of the IFU, and there's a section under Performance, and it indicates at the very bottom Page 5. Let's start over.
Let's go to Page 5 of the IFU, Doctor. There's a little number 5 in the bottom right.
You see it?
A. Yes.
Q. And at the bottom of the page there is a section that says Performance.
A. Yes.
Q. And in that section regarding the mesh material and the Prolift® it says that it "elicits a minimum to slight inflammatory reaction, which is

Page 152

transient." I want to stop there.
Do you have an opinion as to whether that is an accurate statement or not?
A. I have an opinion, yes.
Q. And what is your opinion?
A. It is wrong.
Q. Why do you say that?
A. Because the foreign body reaction as documented in the literature what I've seen in my personal experience and the internal documentation is not minimum to slight, and it is permanent and progressive.
MR. ISMAIL: Objection, move to strike, hearsay.
BY MR. SLATER:
Q. It indicates in the Performance section that there will be "a minimum to slight inflammatory reaction, which is transient, and is followed by the deposition of a thin, fibrous layer of tissue which can grow through the interstices of the mesh."
Do you have an opinion as to whether or not that is a fully accurate and fully fair disclosure of what occurs?
A. I have an opinion, yes.

Page 153

Q. What's your opinion?
A. That it is incorrect.
Q. Why?
A. Based upon my experience, my physical exam of hundreds of women, it is not a thin, fibrous layer. It's thick, it's bunched up, it's firm.
MR. ISMAIL: Move to strike under 403.
BY MR. SLATER:
Q. In the Performance section, about halfway down through that it says, "the mesh remains soft and pliable."
Do you see that statement? Do you have an opinion as to whether that is accurate?
A. It is false.
Q. Why do you say that?
A. That's based upon my own physical exams on patients, review of the literature, review of internal documents. It gets firm and fixed, rigid.
MR. ISMAIL: Objection, move to strike as hearsay, 403.
BY MR. SLATER:
Q. Did you see testimony of Axel Arnaud, the medical affairs director in France with regard to whether the mesh stays soft?

Page 154

A. I saw his and other people's depositions, yes.
Q. And what did he say about whether it stays soft over time?
A. It does not.
Q. Now, there are statements in the IFU regarding the indications or contraindications, and I want to ask you a question -- and we'll have to go back to an exhibit we used previously. I want to ask you a question about who the appropriate patients are for the Prolift® as stated in the IFU.
So, first of all, PLT0062 was one of the first exhibits we used. If you just put that aside, we're going to need that -- let me start over.
Doctor, on Page 2 of the IFU it says Indications right towards the top and it says it's indicated for tissue reinforcement and long-lasting stabilization of the fascial structures of the pelvic floor, et cetera.
You see that?
A. Yes, I do.
Q. And then on Page 6 there are contraindications listed at the very top.
You see that, the very top of the page?

Page 155

A. Yep.
Q. Is there anywhere in this IFU where it's indicated that the Prolift® is intended only for advanced prolapse Stage III or IV?
MR. ISMAIL: Objection, lack of relevance, 403.
THE WITNESS: It does not state anything in regard to indication of a prolapse stage.
BY MR. SLATER:
Q. And let's go now in Exhibit PLT0062 to Page 587, the second to last page of that exhibit, and this is the article by the TVM group, the doctors who developed the Prolift®?
A. Yes, by the inventors of the product, yes.
Q. And right in the middle of the conclusion it says, "this technique should be reserved to the management of grade 3 and 4 prolapse, possibly as first-line treatment."
Do you see that?
MR. ISMAIL: Objection, hearsay, lack of relevance, 403.
THE WITNESS: Yes, I do.
BY MR. SLATER:
Q. Is that of significance to you?

Page 156

MR. ISMAIL: Same objections.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Why?
MR. ISMAIL: Same objection.
THE WITNESS: The surgeons who at this point in time have the largest experience about this product and what it'd be indicated for and including the complications felt that it should be reserved only for the more severe prolapses.
BY MR. SLATER:
Q. And when they say possibly as first-line treatment, what does that mean?
MR. ISMAIL: Same objections.
THE WITNESS: It means that for an individual who comes in who has never had a previous prolapse repair, that may be in their opinion for the higher grade prolapses, it can be used as first-line treatment.
BY MR. SLATER:
Q. And is that significant to you?
MR. ISMAIL: Same objections.
THE WITNESS: Very much so, as a surgeon.
BY MR. SLATER:

Page 157

Q. With regard to the information in the IFU, is that significant to you?
MR. ISMAIL: Same objections.
THE WITNESS: Well, absolutely. As a surgeon who when papers originally come out, you look to the original authors to say, help me, guide me through this and when this is indicated. So, yeah, it's a very important statement for me.
BY MR. SLATER:
Q. Do you have an opinion as to whether that information should have been included in the Prolift® IFU?
A. The surgeons --
MR. ISMAIL: Objection.
BY MR. SLATER:
Q. Do you have an opinion on that?
A. Yes.
Q. What is your opinion as to whether that information should have been provided?
MR. ISMAIL: Objection, lack of relevance, 403.
THE WITNESS: It should have been.
BY MR. SLATER:

Page 158

Q. Why is that?
MR. ISMAIL: Same objections.
THE WITNESS: Because these surgeons are the authority at this point in time. They have the most experience. They know the good and the bad of this product, and so they're saying be careful, only put this in high grade prolapses, maybe as a first line treatment. They're not recommending that. So that's the kind of information I want relayed on by an industry.
MR. ISMAIL: Objection, hearsay, move to strike.
BY MR. SLATER:
Q. And when you give that opinion, you're not just talking about for yourself, you're giving that opinion as to what surgeons, in general, would need?
MR. ISMAIL: Same objections.
THE WITNESS: Absolutely, I'm an educator. I'm teaching the next generation of surgeons. I'm also involved in SUFU, the Society of Urodynamics and Female Urology, where we're trying to teach all those out in private practice. So, yeah, we have to rely on these

Page 159

guidelines to help us point at the best way to treat patients.
BY MR. SLATER:
Q. Okay. We'll go to next exhibit now, PLT0516. This is an article by Dr. Withagen, "Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse, A Randomized Controlled Trial."
Are you familiar with this article?
A. Yes. And this should be pointed out that this was first study where she's doing this work and then we had a follow-up study that we've already reviewed with the complications as a result of this procedure.
Q. All right. Let me ask you the question again.
Doctor, are you familiar with this article?
A. Yes, I am.
Q. Is this article medically reliable and authoritative?
A. Yes, it is.
Q. Is this something you've relied on in forming your opinions?
A. Definitely.

Page 160

Q. Right on the front it talks about the fact that we with these Prolift® patients, the bottom of the results section, "Mesh exposure was detected in 14 of 83 patients (16.9%)."
Is that significant to you?
MR. ISMAIL: Objection, hearsay. Standing objection, please.
MR. SLATER: Yes.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Why?
A. Because in this high volume, talented individual or these surgeons, they had essentially 17%, to be specific, 16.9% risk of mesh exposure at only 12 months. Remember, this is a device that's going to be in a woman forever, and at one year already 16.9% have exposure.
Q. Do you have an opinion as to whether that level of a mesh exposure rate is acceptable or unacceptable from a medical standpoint?
A. It is unacceptable, yeah, absolutely it's unacceptable.
Q. Let's go to the last page of the article, Page 250, the last paragraph. And the second sentence

Page 161

of the last paragraph says, "Because the long-term effects and safety of mesh-reinforced repairs are not yet fully known, surgeons may consider these procedures primarily for recurrent vaginal prolapse after counseling patients on the risks and benefits."
Is that statement significant to you?
A. Yes.
Q. Why?
A. Once again, in this high volume surgeon, they're saying that even as of 2011, we still don't know the true complications that can occur with this, and so it only should be reserved for individuals with a recurrent prolapse. They have already had a surgery and it's failed and it needs surgery again. So it's reserving it for a very small subgroup.
Q. And, in your opinion, do you think -- rephrase.
Do you have an opinion as to whether the IFU should have limited the scope of patients who would be acceptable, candidates as listed in that article by Withagen?
MR. ISMAIL: Objection, sorry. In addition to hearsay, cumulative, 403.
THE WITNESS: Absolutely, I have an

Page 162

opinion about it.
BY MR. SLATER:
Q. What is that?
MR. ISMAIL: Same objection.
THE WITNESS: It should have been listed.
BY MR. SLATER:
Q. Let's go to the next exhibit.
Doctor, looking at Exhibit P980, it's some e-mails, January of 2005, about two months before the Prolift® went on the market.
Are you familiar with this e-mail chain?
A. Yes, I've seen it.
Q. What I'd like to do is turn to the second page, e-mail from Axel Arnaud, the medical affairs director at Ethicon in France, and he's proposing a warning.
And have you seen this e-mail and this proposed warning?
A. Yes, I have.
Q. And just for the record, I'll read it and then I have to ask you a question.
"Warning: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as

Page 163

vaginal erosion and retraction which can result in anatomical distortion of the vaginal cavity which can interfere with sexual intercourse. Clinical data suggest the risk of such an complication is increased in the case of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman."
Now, do you have an opinion as to whether or not that warning should or should not have been provided in the Prolift® IFU?
A. I have an opinion on it, yes.
Q. What is your opinion?
A. Absolutely, it should have been.
Q. Why do you say that?
A. Well, you have an individual, Arnaud, who knows the data, has seen what's happened with internal documentation, and he is warning -- he saw the problems that were occurring, knew about the problems and wants to put in the IFU a warning to doctors saying patients need to be told about this.
MR. ISMAIL: Objection, move to strike, improper expert testimony.
BY MR. SLATER:
Q. With regard to sexually active women, do

Page 164

you have an opinion as to whether or not a warning was needed to cull out the specific risks for sexually active women?
A. Absolutely, because of the risk of dyspareunia, yeah. You need to be able to tell them, you have a potential for problem and not be able to have intercourse without pain in the future.
Q. Doctor, let's go back to the IFU, Exhibit P1005. You have it right there. Okay. Start over.
Doctor, looking at the IFU, let's look at the last page, and it has a list of adverse reactions.
Do you see that?
A. Yes, I do.
Q. And it says, "Potential adverse reactions are those typically associated with surgically implantable materials." I want to stop there.
Surgically implantable materials, is that limited -- is that group of materials just mesh, or is that a bigger group?
A. Well, as they state there, surgically implantable materials is anything, that can be a heart valve, knee joint, hip joint. It could be anything.
Q. In your opinion, is it accurate, medically accurate to say that for mesh, the Prolift® mesh in

Page 165

actual use that the potential adverse reactions are those typically associated with surgically implantable materials in general?
A. No, not at all.
Q. Why do you say that?
A. I mean, the type of complication, the severity, the chronic nature, the progressive nature is different than in other types of implants. I do implants on different types of things in males. I'm the number one implanter in the United States, and we don't see what we're seeing with these females. So you can't -- you can't compare all surgical implants. We're dealing with a vaginal mesh.
Q. Let me read in the adverse reactions, there's certain language. They mention erosion and extrusion.
Do you see those? They're listed in that list of adverse reactions typically associated with surgically implantable materials?
A. Yes, I do.
Q. Is it adequate, in your opinion, from a medical standpoint to simply list erosion and extrusion, as done there, to communicate the risks of erosion and extrusion?

Page 166

A. No, it's wholly inadequate.
Q. Why?
A. It's insufficient, it gives us no idea of the frequency, the severity, recurrent nature, the lifelong risk of erosions and extrusions.
Q. It says with regard to potential adverse reactions typically associated with surgically implantable materials "scarring that results in implant contraction."
Do you see that?
A. Yes, I do.
Q. Is that an adequate description of the risk of scarring and implant contraction?
A. No.
Q. Why is that?
A. Again, like I mentioned, it has no idea of the ramifications, the severity of it, the progressive nature of it, the life-changing disability and the inability to fix it.
Q. Doctor, let's go to the next Exhibit P1557. This is an e-mail written by David Robinson, October 28, 2005.
Are you familiar with this e-mail?
A. Yes, I am.

Page 167

Q. In this e-mail, David Robinson says he is aware of four cases of Prolift®s done in folks with normal preoperative voiding function who post Prolift® can't void.
Do you see that?
A. Yes, I do.
Q. He says a little further down, some have resolved spontaneously but have taken as long as a year to do so and asks the person he's writing to if they've seen the -- this complication, this is right before he joined the company as medical director?
MR. ISMAIL: Objection to the use of this document as hearsay.
BY MR. SLATER:
Q. Correct?
A. Yes.
Q. And David Robinson says -- and it's actually addressed to Marty, that would be Marty Weisberg, medical director, if this starts getting reported, it's going to scare the daylights out of doctors.
Do you see that?
MR. ISMAIL: Same objection.
THE WITNESS: Yes, I do.

Page 168

BY MR. SLATER:
Q. From your standpoint as a physician in clinical practice and teaching residents and an author of articles, is that of significance to you?
MR. ISMAIL: Objection, hearsay, improper grounds for expert testimony.
THE WITNESS: Absolutely, yes.
BY MR. SLATER:
Q. Why is that significant to you?
MR. ISMAIL: Same objections.
THE WITNESS: Because it's true. We're trained not to harm people, make them worse. That's the whole goal of medicine. So now they're saying now they're trying to cover up a potential complication.
MR. ISMAIL: Move to strike, nonresponsive, 403, improper grounds for testimony.
BY MR. SLATER:
Q. Let me ask you this question: Where it says that if this starts getting reported that people were having the inability to void, they were having urinary retention that was lasting for a year or more and if it gets reported it's going to scare the

Page 169

daylights out of doctors, why, in your opinion, is that significant?
MR. ISMAIL: 403, cumulative, hearsay, improper grounds for expert testimony.
THE WITNESS: It's a unique complication that would not necessarily be seen. You don't see this with traditional repairs. So this is a unique thing. They're talking bladder atony, which means there's no function to the bladder, so the nerves going to the bladder have been disrupted by this procedure.
BY MR. SLATER:
Q. Does the IFU adverse reactions list warn of urinary complications, such as retention or urinary dysfunction due to the Prolift® itself?
A. No.
Q. Do you have an opinion as to whether or not it should have?
A. Absolutely it should have.
Q. Okay. Let's go back to Exhibit P1306, patient brochure. You have it up there from beginning of the dep, it's right there, and I think -- let me take a step back.
Have you in your practice seen and used patient

Page 170

brochures?
A. Yes.
Q. You understand or do you understand the use for which they're supposed to be made?
A. Yes, I do, and I give them out daily.
Q. I want to pull up a slide, the last slide, Prolift® patient brochure, and what we'll do is with the brochure in hand, we'll go through certain things that the brochure says.
MR. ISMAIL: Objection.
BY MR. SLATER:
Q. In the interest of time.
MR. ISMAIL: Objection, to the use of the document, 403, lack of relevance in this case.
BY MR. SLATER:
Q. Let's do this, looking at the brochure itself, Page 10. Let's take down the slide -- let me stop. Let's leave the slide up for a second. I want to ask you a question about the slide, Doctor.
Is this a summary of issues you have with the information provided in the brochure?
A. Yes.
Q. And are we going to now go through those issues specifically within the brochure?

Page 171

A. Yes.
Q. Now let's go to the brochure.
MR. ISMAIL: Object to use of the slide on the same grounds.
BY MR. SLATER:
Q. Page 10, let me ask you this about the slide that we have up.
Do you have an opinion -- well, rephrase. We'll come back to it. Stop. Let me clean this up.
Looking at the patient brochure, Page 10, it says "What is Gynecare Prolift®" at the very top. "A revolutionary surgical procedure using Gynecare Prolift® employs a specially designed soft mesh placed in the pelvis to restore pelvic support."
Do you have an opinion as to whether or not that is adequate and accurate information regarding the Prolift®?
MR. ISMAIL: Objection, lack of relevance, 403.
THE WITNESS: Well, it's a long sentence. Certain parts of it are correct, other parts are incorrect.
BY MR. SLATER:
Q. Let's talk about it. Let's talk about

Page 172

calling it a revolutionary surgical procedure. Is that statement, in your opinion, something that should be included here?
MR. ISMAIL: Objection, lack of relevance, 403.
THE WITNESS: I think that is actually an acceptable statement. It was new, it was different, no one had done it before, and it was revolutionary, and therein lies the problem that many doctors don't know a thing about it, and so they have to be taught.
BY MR. SLATER:
Q. It says it was a specially designed supportive soft mesh.
Was that an accurate statement, to your knowledge?
MR. ISMAIL: Objection, 403, lack of relevance.
THE WITNESS: It's false.
BY MR. SLATER:
Q. And why is that?
A. Because it was designed for hernias, not vaginal meshes.
Q. When it refers to it as being soft mesh,

Page 173

in actual use, does the mesh remain soft?
MR. ISMAIL: Objection, cumulative, 403, lack of relevance.
THE WITNESS: Well, that's what we discussed, in my own personal experience and review of the internal documents and papers, manuscripts, it does not stay soft. It gets firm, rigid.
BY MR. SLATER:
Q. On Page 10 under "What is Gynecare Prolift®," towards the bottom it says, it's "performed through very small incisions inside the vagina."
Do you see that? First paragraph right there under "What is Gynecare Prolift®," the second sentence.
A. Yes, I see it.
Q. Is the Prolift® only placed through very small incisions, or does that accurately describe the trocars and the cannulas?
MR. ISMAIL: Objection, lack of relevance, 403.
THE WITNESS: Well, no, it's not only performed through the vagina. There are also obturator incisions, and the incision is variable from 2 to 4 to 5 centimeters, so it

Page 174

depends how you want to define very small.
BY MR. SLATER:
Q. Doctor, with regard to the brochure, let's go to Page 13, and it says, "What are the risks? All surgical procedures present some risks. Although rare," and I'm going to stop there.
Do you have an opinion as to whether or not it is accurate to describe the risks with the Prolift® as rare?
MR. ISMAIL: Objection, lack of relevance, 403.
THE WITNESS: It is wrong, incorrect.
BY MR. SLATER:
Q. Why do you say that?
MR. ISMAIL: Same objection.
THE WITNESS: It's just not my opinion, that's also Axel Arnaud. He says it's rather common.
MR. ISMAIL: Objection, move to strike, improper testimony.
BY MR. SLATER:
Q. It says at the bottom of the section What are the risks, there is a small risk of the mesh material becoming exposed into the vaginal canal."

Page 175

Do you have an opinion as to whether or not that is an accurate statement?
MR. ISMAIL: Objection, 403, lack of relevance.
THE WITNESS: Yes, I do.
BY MR. SLATER:
Q. And what is your opinion?
A. False.
Q. Why do you say that?
MR. ISMAIL: Same objections.
THE WITNESS: Based upon my clinical experience, the review of the medical literature and internal documents, the risk is actually very common.
BY MR. SLATER:
Q. On Page 13, towards the bottom, under "Is Gynecare Prolift® right for me?" It says, "Pelvic floor repair procedures with Gynecare Prolift® are appropriate for most patients." I want to stop there.
Do you have an opinion as to whether that is an accurate statement?
MR. ISMAIL: Lack of relevance, 403.
THE WITNESS: Yes, I do.
BY MR. SLATER:

Page 176

Q. And what is your opinion?
MR. ISMAIL: Same objection.
THE WITNESS: It's incorrect based upon the medical literature.
BY MR. SLATER:
Q. Why do you say that?
A. Because the inventors of the product and other researchers coming out saying it needs to be for high grade and recurrent prolapse.
MR. ISMAIL: Move to strike, hearsay.
BY MR. SLATER:
Q. Doctor, do you have an opinion as to whether or not the Prolift® patient brochure provides an accurate picture of the risk-benefit profile for the Prolift® for a doctor or a patient?
MR. ISMAIL: Objection, lack of relevance, 403.
THE WITNESS: I have an opinion, yes.
BY MR. SLATER:
Q. And what is your opinion?
MR. ISMAIL: Same objection.
THE WITNESS: It is insufficient and inadequate.
BY MR. SLATER:

Page 177

Q. Doctor, with regard to the Prolift® IFU, do you have an opinion to a reasonable degree of medical certainty as to whether the IFU provides an adequate and accurate picture of the risk-benefit profile for the use of the Prolift®?
MR. ISMAIL: Cumulative.
THE WITNESS: I have an opinion, yes.
BY MR. SLATER:
Q. What is your opinion?
MR. ISMAIL: Same objection.
THE WITNESS: It is insufficient and inadequate.
BY MR. SLATER:
Q. And is that for with regard to the patient brochure, your opinion, is that based upon all the things you've told us during your testimony with regard to the nature of the Prolift® and the risks?
A. Absolutely.
Q. With regard to the IFU, is your opinion based upon the information you've given us throughout your testimony regarding the nature of the procedure, the risks and the other things you've told us about the Prolift®?
A. Yes.

Page 178

MR. SLATER: Let's go off.
THE VIDEOGRAPHER: The time is 12:24, and we're off the record.
(Brief recess.)
THE VIDEOGRAPHER: The time is 12:40 and we are back on the record.
MR. SLATER: Dr. Elliott, thank you very much. I think there will be some cross-examination from defense counsel.
CROSS-EXAMINATION
BY MR. ISMAIL:
Q. Good afternoon, Doctor.
A. Good afternoon.
Q. Are you prepared to proceed with cross-examination at this time?
A. Yes, I am.
Q. Doctor, you testified this morning about potential complications you believe that are associated with the use of transvaginal mesh for treatment of organ prolapse, correct?
A. Correct.
Q. Now, I will get to your general views later but, can you confirm that not every patient who received transvaginal mesh for treatment of prolapse

Page 179

experienced one of the complications you described this morning?
MR. SLATER: Objection. You can answer.
THE WITNESS: At this point in time, as of November 21st, 2015, those patients -- not all patients have experienced all those complications.
BY MR. ISMAIL:
Q. And that's true for the Prolift® as well, right?
A. That is correct.
Q. Before anyone can conclude that a patient experienced any of the complications from a Prolift® device you would need to consider the specifics of that patient, correct?
A. You have to look at the entire patient, all the medical history and their surgical procedures, yes.
Q. Okay. So let's just make sure we're making ourselves clear here. So what you would want to look at to know whether a patient has experienced a complication from a Prolift®, you would want to look at patient medical records, correct?
A. That would be part of it, yes.

Page 180

Q. You would want to consider what symptoms the patient reported and when, correct?
A. Chronology of onset of symptoms, yeah, that would be an important factor.
Q. You would want to consider, in this analysis that we're describing, what other procedures or surgeries that patient had in the relevant time frame, correct?
A. Yeah, you would want to look at the concurrent surgeries and past surgeries, yeah, that's right.
Q. You would want to consider the findings of that patient's healthcare provider with respect to the patient's symptoms and complaints, correct?
A. Well, that would be the medical records, yeah, with the caring physician's report, yes.
Q. And you have done none of that with respect to Patricia Hammons, correct?
A. Incorrect.
Q. Let me rephrase.
You did not disclose anywhere in your expert report any opinions relating to Ms. Hammons, correct?
A. I did -- not specific to Ms. Hammons, no.
Q. You did not disclose anywhere in your

Page 181

expert report having reviewed Ms. Hammons' medical records, correct?
A. I don't recall if I have reviewed her records but I didn't -- not in the expert report I don't believe.
Q. You didn't disclose anywhere in your expert report that you reviewed the sworn testimony in this case, correct?
MR. SLATER: Objection.
BY MR. ISMAIL:
Q. The sworn testimony in Ms. Hammons' case, correct?
A. You mean her --
MR. SLATER: Let me just clarify. When you say in Ms. Hammons' case, you are talking about of her or --
MR. ISMAIL: I'll clarify.
THE WITNESS: Sworn testimony, you mean her deposition?
MR. ISMAIL: I will rephrase, Doctor.
THE WITNESS: Okay.
BY MR. ISMAIL:
Q. Nowhere in your expert report do you disclose that you reviewed the sworn testimony of

Page 182

Ms. Hammons, correct?
A. I don't recall disclosing that, no.
Q. Nowhere in your expert report did you disclose reading the sworn testimony of Ms. Hammons' healthcare providers, correct?
A. I don't believe so. Again, I'd have to look at the report. I don't recall making that statement one way or the other actually.
Q. Nowhere in your expert report do you disclose doing a physical exam on Ms. Hammons, correct?
A. That would be correct, yes.
Q. And you have not done a physical exam on Ms. Hammons, correct?
A. No, I have not, no.
Q. So my statement is correct?
A. Yes.
Q. And you have previously said, Doctor, that a physical examination is one of the most important pieces of the puzzle in understanding what happened to a patient, correct?
A. That's a fair statement, yes.
Q. And certainly, Doctor, you can confirm that in some patients Prolift® was effective in relieving symptoms of the patient's pelvic organ

Page 183

prolapse, correct?
A. That does happen at times, yes.
Q. And not just an improvement in the patient's symptoms, but, actually, a Prolift® can improve a patient's quality of life, that has been reported, correct?
A. That has been reported, yes.
Q. And before you can determine whether a patient has had an improvement in her quality of life you would want to look at the same things we have already discussed; the medical records, the timing of her symptoms, findings of her healthcare providers, et cetera, correct?
A. That is correct.
Q. And nowhere in your expert report do you disclose doing any of that analysis for Ms. Hammons, true?
A. I don't disclose that, you are correct.
Q. Now, you have discussed your views on Prolift® in response to questions from Mr. Slater this morning, right?
A. Yes.
Q. And you did so as a paid witness on behalf of the plaintiff lawyers, correct?

Page 184

A. That is correct.
Q. You were first contacted in September of 2011; do you recall that?
A. August, September of '11, yes.
Q. Okay. So I want the jury to understand your experience with Prolift® before the time that you were hired by the plaintiff lawyers in this litigation, okay?
A. Okay.
Q. Now, you, yourself, have never performed a Prolift® surgery for the implantation of a Prolift®, correct?
A. By choice, you are correct, yes.
Q. So when you were walking the jury through this morning, in the event that video is shown at trial, the surgery of a Prolift® being implanted in a patient, you never have done that yourself, correct?
A. That is correct, by choice I did not, yes.
Q. And that surgical video you never saw prior to being retained by the plaintiff lawyers in this litigation, correct?
A. That specific video I did not, you are correct.
Q. In fact, Doctor, you never received any

Page 185

training whatsoever on Prolift®, true?
A. That would be correct, yes.
Q. You walked through or at least referenced a -- something that Mr. Slater introduced as a professional education PowerPoint.
Do you recall seeing that this morning?
A. Yes, I do.
Q. Prior to being hired by the plaintiff lawyers in this case you had never seen any professional education materials submitted by Ethicon on Prolift®, correct?
A. Not that I recall but I've been to their -- their Ethicon booth when this first came out, so I don't recall what I saw back then.
Q. When you say you went to the Ethicon booth, you are saying to the extent Ethicon had a booth at a medical conference, you might have stopped by --
A. Yeah.
Q. -- and you can't recall whether you saw anything on Prolift® in such visit; is that fair?
A. No. We would have seen it on the Prolift®. I don't recall what I saw. It was a long time ago. It was when it first came out.
Q. All right. Let me rephrase my question

Page 186

then.
You never attended any type of professional education courses that Ethicon sponsored for Prolift®, true?
A. You are correct, yes.
Q. Now, you never participated in any professional education courses sponsored by any manufacturer of a transvaginal mesh for treatment of pelvic organ prolapse, correct?
A. Well, that -- that's what we clarified earlier. I was in attendance and an instructor AMS as far as with the sling and then went over and implanted their device on the cadaver. I was not a formal student because I was an instructor for slings, but, again, I just walked over to the next cadaver and did it.
Q. All right. Let's make sure the jury understands what you are saying. When you are saying that's something that I clarified earlier, you recall saying something different in your sworn deposition testimony in this case?
A. My deposition in 2011 or 2012 maybe the year was, I stated I was never a formal student in any class, which is correct. I was not a formal student.

Page 187

That's why how do we define it? I was not a formal student, I did not take a formal class but I have implanted with the instructor there so I don't know how we define myself, to be clear.
Q. All right. Let me just break that down into chunks if you don't mind, Doctor.
Previously when you were asked whether you attended any professional education training for a transvaginal mesh for pelvic organ prolapse your answer was that you had not, correct?
A. Which would be correct, yes.
Q. And what you are trying to clarify is that while you were at a training for a different medical device, you went over to some training happening on a transvaginal kit for -- by a different manufacturer?
A. By AMS, that's correct.
Q. Okay. So even with the clarification that you have added today, it's still true that you have never attended any professional education for Prolift®?
A. Correct.
Q. And your answer you referenced cadaver training. Can you please tell us what cadaver training is?
A. It would be a workshop using a non-live

Page 188

human cadaver, fresh frozen cadaver, where you just have the pelvis to work with to insert the trocars through the obturator foramen, vaginal dissection and those types of things.
Q. And cadaver training is sometimes used for surgeons to gain familiarity with a new surgical procedure?
A. Correct.
Q. And you had never done any cadaver training on Prolift®, correct?
A. Correct.
Q. Now -- one second, Doctor.
Here's my question, at the time of your deposition you testified that you never underwent any cadaver lab training with respect to transvaginal placement of mesh, and you still stand behind that comment, true?
A. That's correct. Again, it's a matter of defining how we define what I did.
Q. Now, before being hired by the plaintiff lawyers in this case you had never observed a surgery involving Prolift®, correct?
A. Probably would be accurate, yes.
Q. Now, you have no research experience on

Page 189

Prolift® as well; isn't that true, Doctor?
A. Correct.
Q. You have never participated in any clinical trials that relate to Prolift®, true?
A. Specific Prolift®, you are correct, yes.
Q. You haven't participated in any clinical trials relating to transvaginal mesh or the use of transvaginal mesh in the treatment of pelvic organ prolapse; isn't that correct, Doctor?
A. Correct.
Q. You have never done any -- withdrawn.
You referenced earlier something called Level 1 evidence; do you recall making that reference?
A. I don't recall but I don't doubt I said it.
Q. Is randomized controlled clinical trials an example of Level 1 evidence?
A. Yes.
Q. You have never been involved in any randomized controlled clinical trials involving the use of mesh in any application, correct, Doctor?
A. Meshes, you would be correct, yes.
Q. You've never been involved in any clinical study that used transvaginal mesh to treat pelvic organ

Page 190

prolapse, true?
A. Transvaginal meshes, I don't recall. No, I don't believe so.
Q. So my statement is correct?
A. Yes.
Q. You've never been involved in any prospective studies involving the use of mesh, correct?
A. Correct.
Q. You have never been involved in a clinical trial designed to evaluate the safety and efficacy of a transvaginal mesh in any application, correct?
A. Correct.
Q. Are you familiar with meta-analyses, Doctor?
A. Yes.
Q. Can you please tell us what they are?
A. Meta-analysis is just a statistical way of analyzing multiple different studies, studies you have not performed but using other people's datas and analyzing them.
Q. Are meta-analyses a way that researchers can summarize the clinical evidence that have been published on a surgery?
A. Possibly.

Page 191

Q. You have not done any meta-analyses involving the use of transvaginal mesh, true?
A. Correct.
Q. You indicated, Doctor, a couple times that you currently practice at Mayo in Minnesota?
A. Correct.
Q. You're not here today testifying as a representative of the Mayo Clinic; isn't that correct, Doctor?
A. That would be -- I guess accurate, yes.
Q. Mayo has not sanctioned your activities working as a paid witness on behalf of the plaintiff lawyers in this case, true?
MR. SLATER: Objection.
THE WITNESS: No, this is on my private time.
BY MR. ISMAIL:
Q. In fact, the Mayo Clinic does not even know that you are serving as an expert for the plaintiffs in this case, correct?
A. As I stated, it's all in my private time.
Q. So the answer to my question is what, sir?
A. That is correct, it's all in my private time.

Page 192

Q. I'm trying to make a distinction, Doctor, between you saying it's on your private time and whether your hospital even knows you are doing this activity, so let me restate the question so you have it in mind.
The Mayo Clinic does not even know that you are serving as an expert on behalf of the plaintiffs in this litigation, true?
A. That is correct, it is all done in my private time.
Q. Have you disclosed to the Mayo Clinic the money you have received from the plaintiff lawyers in this litigation?
A. No, I have not.
Q. But you have, in fact, received money from the plaintiff lawyers in this case, correct?
A. That is true.
Q. How much per hour are you being paid, sir?
A. 700.
Q. When you say "700", that's $700 per hour?
A. Correct.
Q. How much has Mr. Slater paid you thus far?
MR. SLATER: You are talking about in this case?

Page 193

BY MR. ISMAIL:
Q. I'm asking how much Mr. Slater has paid you since the time Mr. Slater began paying you.
A. I have no idea. I don't even bill Mr. Slater.
Q. Whom do you bill?
A. Mr. --
MR. SLATER: Let's take a step back here. There's an understanding that witnesses are to be questioned about the fees they're paid in a particular case and that's how it's been done throughout and that's been our understanding in this case. You may not be aware of that but it's been how it's been handled in the depositions and that was our understanding.
So if you are asking about in the Hammons case, you know, that's fine, but to start talking about overall litigation or other cases, it's understood and it's on the record, probably in the deposition of Dr. Weber, that we were not going to get into billing outside the specific case.
MR. ISMAIL: Well --
MR. SLATER: And, in fact, that's how it

Page 194

was handled in the Bellew trial in the MDL and I think that's the understanding everybody has about how we're handling this on both sides.
MR. ISMAIL: So how about he gives the answer -- since we're not going to call him back here and redo this, he gives the answer and if we don't play it to the jury, we don't play it to the jury.
MR. SLATER: I'm not going to allow him to testify beyond what he's been paid in this case because we have an agreement between counsel and I'm not going to have someone walk in on cross-examination and change the ground rules in the middle of cross.
MR. ISMAIL: That's not an agreement to which I am privy.
MR. SLATER: You are bound to it though, co-counsel --
MR. ISMAIL: Can I finish my statement? Not an agreement to which I -- that I've heard of and so I'm going to ask the question and it's up to you as to whether you are going to let him answer.
MR. SLATER: I will only allow him to

Page 195

answer questions about what he's been paid in this case, so you don't need to ask the questions as a formality because I'm not going to allow him to answer them because we have an agreement with counsel.
MR. ISMAIL: I'm going to ask the question and you can do what you want.
BY MR. ISMAIL:
Q. Dr. Elliott, how much have you been paid by the plaintiff lawyers who are suing Ethicon?
MR. SLATER: Don't answer the question and the question is improper anyway.
BY MR. ISMAIL:
Q. Are you going to refuse to answer the question, Doctor?
MR. SLATER: No, no, you are not even going to ask him that --
MR. ISMAIL: Yes.
MR. SLATER: -- because I have instructed him not to.
MR. ISMAIL: He has to right to -- you have given your instruction, he can still answer the question if he wants.
THE WITNESS: I'm following Mr. Slater's

Page 196

advice to not answer the question.
MR. ISMAIL: I will limit my question.
BY MR. ISMAIL:
Q. How much have you been paid with respect to your work on behalf of the plaintiff lawyers in the Prolift® litigation?
MR. SLATER: Objection, same thing, don't answer.
BY MR. ISMAIL:
Q. Are you going to refuse to answer my question, Doctor?
A. I'm not going to answer based on Mr. Slater's recommendation.
Q. Isn't it true, Doctor, you submit an invoice every month for your work on behalf of the plaintiffs' lawyers and you have since 2011?
MR. SLATER: Objection.
THE WITNESS: Well, not every month, only if work is done.
BY MR. ISMAIL:
Q. How many of the months since 2011 have you submitted an invoice?
MR. SLATER: Objection. All these questions he's -- obviously, these are back

Page 197

door -- I'm going to object to the whole line of questions. I mean, it's generalized about how often he submits invoices is fine, but I object to this.
I mean, sir, there's an agreement between counsel. It's a little frustrating when someone walks in and says, well, sorry, I wasn't there. Maybe they need to prep you better.
BY MR. ISMAIL:
Q. And your answer, sir?
A. Oh, I have no idea, looking back, of how many times I do and don't because there are sometimes I don't do any work for months.
Q. Doctor, have you estimated that you have on average spent 20 to 30 hours a month working on behalf of the plaintiff lawyers in this litigation?
MR. SLATER: Objection. Now --
MR. SPECTER: What's "this litigation"? Beyond that.
MR. ISMAIL: You can state your objection, you can instruct him not to answer. We don't have to argue about it. If it doesn't get played, it doesn't get played.

Page 198

MR. SLATER: But it's not the point because if it doesn't get played, it doesn't get played is not really a legitimate answer to that because you are creating a record of things that we had an agreement were not going to be asked about.

MR. ISMAIL: And if you're right what's the --

MR. SLATER: And it goes both ways, by the way. Your experts don't want to be asked these questions either.

MR. ISMAIL: If you're right, you're right. I still don't understand what the -- you make your objection and instruct him not to answer. I don't understand why we're even arguing about it.

MR. SLATER: Well, because it's frustrating that -- you know, you are pretending you don't know there was an agreement.

BY MR. ISMAIL:

Q. So let me restate the question so you have it in mind, Doctor.

A. Thank you.

Page 199

Q. Have you worked on average 20 to 30 hours a month on behalf of the plaintiff lawyers since approximately 2011?

MR. SLATER: Objection.

MR. SPECTER: Can I ask you to clarify though, counsel. Are you asking about the Hammons litigation or are you asking about the litigation in general?

MR. ISMAIL: Well, since the Hammons litigation wasn't filed in 2011, I suspect that would be difficult.

MR. SLATER: Yeah, well, no one knows that.

MR. SPECTER: The jurists know that, counsel. Please.

MR. ISMAIL: So the question is there. If you don't want him to answer --

MR. SPECTER: I'm just asking you to clarify your question, counsel. Are you asking about the Hammons litigation or are you asking about litigation in general?

MR. ISMAIL: My question goes to the issue of bias, the amount of money the witness has been paid and if you don't want him to answer the question, tell him not to answer the question.

Page 200

MR. SPECTER: I'm not asking about what the question goes to. I'm simply asking whether the question goes to the Hammons litigation or the TVM litigation in general.

I take it from what you are saying you are asking about the TVM litigation in general?

MR. ISMAIL: I'll rephrase.

BY MR. ISMAIL:

Q. Doctor, the report that you submitted in this case, in Ms. Hammons' case, does that date back to work that you started doing on behalf of the plaintiff lawyers when you were first retained in 2011?

MR. SLATER: Objection. You can answer.

THE WITNESS: I don't quite know how to answer that question. Not to be evasive by any means, I've been doing work for the past 20 years on prolapse and complications so that specific document, I probably have done work earlier that was translated to it as far as the background and those types of things, but, again, I can't be specific. I just don't know.

BY MR. ISMAIL:

Page 201

Q. I'll rephrase.

You have looked at materials that were sent to you by the plaintiff lawyers in this case, correct?

A. Correct.

Q. Mr. Slater has sent you materials, correct?

A. Yes.

Q. You have looked at some internal depositions and documents about the Ethicon employees, correct?

A. Yes.

Q. And you have referenced them during your testimony today?

A. That is correct.

Q. And you have included them in your expert report submitted in this case?

A. That is correct.

Q. Some of the work that you did that resulted in the expert report submitted in Ms. Hammons' case dates back to 2011/2012 time frame, correct?

A. That would be correct, yes.

Q. So with that understanding, Doctor, can you tell me the amount of money that you have been paid by the plaintiff lawyers for that work?

MR. SLATER: Objection. Don't answer the question.

THE WITNESS: I'm not going to answer the question based on Mr. Slater's recommendation.

BY MR. ISMAIL:

Q. Doctor, Prolift® was designed to treat pelvic organ prolapse, correct?

A. That is correct.

Q. Since we're not exactly sure when the jury is going to see this video, I don't know if this has been defined for them yet, but for the benefit of the jury, pelvic organ prolapse, in a general sense, when one or more of the patient's internal organs drop into the vagina?

A. Correct.

Q. Their internal organs most often involved include the bladder, the rectum, the uterus and the small bowel, correct?

A. Yes, that would be correct.

Q. And I think you told us earlier that what leads to a pelvic organ prolapse is a weakening of the patient's tissues in the pelvic floor, correct?

A. A weakening, a stretching of the tissues that hold it up, yes.

Q. Now, there are many risk factors that can lead to pelvic organ prolapse, correct?

A. There are several, yes.

Q. These include age, that's a risk factor, right?

A. Yes.

Q. Obesity I think you told us earlier was a risk factor?

A. Yes.

Q. Childbirth is a risk factor?

A. Correct.

Q. Previous surgery for prolapse is a risk factor?

A. Yes.

Q. Previous hysterectomy is a risk factor?

A. Possible, yes.

Q. Menopause?

A. Menopause would be questionable. It's going to be tough to delineate that data because we also have age and menopause, so it's -- it's not helpful, let's put it that way.

Q. Fair enough. And what you are saying is age and menopause often go hand-in-hand and it's difficult to tease out which is the menopause and which

is the age?

A. Correct.

Q. Repeated lifting can be a risk factor for pelvic organ prolapse?

A. That's correct.

Q. Smoking has been reported as a risk factor for pelvic organ prolapse?

A. Again, there is going to be studies out there maybe yes, maybe no, but it's possible.

Q. And, of course, a woman can develop pelvic organ prolapse with just one or even none of the risk factors we've just described, correct?

A. That is correct, yeah, with just one, yes. With none it's rare, but it does occur.

Q. Now, pelvic organ prolapse is assessed on a grading scale for how severe the prolapse is, correct?

A. Yeah, how severe the anatomical prolapse is, yes.

Q. And there -- I think you reference there's a few different grading systems that are out there for clinicians to use, right?

A. There's three or four, yes.

Q. One of which I think you reference was

called the POP-Q system?

A. Correct.

Q. Have you ever used the POP-Q system yourself?

A. I use it not as commonly as the Baden-Walker.

Q. Does the POP-Q system assess how far the woman's internal organs have descended into or beyond the opening of the vagina?

A. That's part of it, yes.

Q. What are the grading -- I don't need the definitions yet, but is it -- it's grades 1 through 4, correct?

A. Yeah, but then you are looking at each component, whether it's anterior, posterior, apical, vaginal length, so it's -- yeah, you can do the 1, 2, 3, 4 but that's gonna -- simplified form of the POP-Q.

Q. And 4 is the most severe grade of pelvic organ prolapse?

A. That is correct.

Q. The other system you reference is the Baden-Walker system; is that correct?

A. There's Baden-Walker and there's also International Continence Society stages. They're all

Page 206

somewhat similar with different bells and whistles one way or the other.
Q. And the Baden-Walker, again, is grades 1 through 4, with 4 being the worst?
A. That's correct.
Q. And that's the one that you prefer in your clinical practice?
A. Correct.
Q. What is the criteria for grade 4 under the Baden-Walker system?
A. Same as for the POP-Q, it's complete eversion out of the vagina.
Q. When you say "eversion" --
A. Means that the vagina has -- everted means -- think of the vagina like a tube sock; somebody reaches in, grabs it and everts out, eversion of the vagina.
Q. And in a grade 4, that is the most severe pelvic organ prolapse a physician can grade for a patient?
A. That is correct, yes.
Q. And in clinical application that means the prolapse is actually visible in the vaginal opening, correct?

Page 207

A. Correct. It can also be visible in stage 2 also, but, yes, it's like a baby's head coming out of the vagina, basically.
Q. Prolapse can be a serious condition for a woman, correct?
A. It depends how you define serious. It can be bothersome. It's very rarely in the United States life-threatening, so it's not along the lines of a cardiac problem that's life and death. Very rarely, I've never seen that.
Q. You used the description several times today of prolapse being a quality of life condition?
A. Correct.
Q. Meaning that a pelvic organ prolapse can negatively affect a woman's quality of life?
A. That is correct, it can.
Q. A pelvic organ prolapse can be debilitating and troublesome to a woman?
A. Yeah, again, debilitating, yes, that can happen. It can be bothersome. I think it's fair to say it's bothersome.
Q. The symptoms that a woman can report include feelings heaviness or pressure, correct?
A. That is something they can feel, yes.

Page 208

Q. You've heard of reports of a woman feeling a bulge or seeing the protrusion from the vagina as a result of the pelvic organ prolapse, correct?
A. That is correct, yes.
Q. Difficulty with walking or sitting have been described in women with pelvic organ prolapse, correct?
A. In severe cases, yes, that does happen.
Q. And what we're describing here can be distressing to many women?
A. Yeah, depends how you want to define many, but a lot of women it can be bothersome, I won't deny that at all. I agree with you.
Q. Let me put it this way, Doctor, you would agree that prolapse can be significant enough that the patient doesn't want to deal with it?
A. That is correct, yes.
Q. You've used this term, dyspareunia, in your testimony. That, in a general sense, means pain with sexual intercourse, correct?
A. That is correct.
Q. There are some women for whom pelvic organ prolapse can actually cause dyspareunia, correct?
A. That is correct. We have to define how

Page 209

severe that dyspareunia is. There's not just -- dyspareunia means only one thing, it can be severity, so I agree with you.
Q. So seeing the description of a patient as having dyspareunia doesn't tell you how severe the dyspareunia is, correct?
A. All it says is like you drive a car, we have no idea of the specifics of it, but it states that there is discomfort with sexual activity.
Q. And, again, without regard to severity, you've confirmed for us already that women with pelvic organ prolapse can have dyspareunia, correct?
A. To a certain degree, yes, they can.
Q. Now, there are I guess a couple different reasons why a woman may not be sexually active who is experiencing pelvic organ prolapse, one of which can be just the pain that pelvic organ prolapse may result for dyspareunia, correct?
A. Correct.
Q. And the prolapsing organ in a woman can actually interfere with sexual activity, correct?
A. It can block it, yes.
Q. But, also, you are aware, Doctor, that for some women the prolapse effects how they feel about

Page 210

themselves and embarrassment being with their partner or their desire to have sexual intercourse, correct?
A. I agree, the psychological aspect of embarrassment can be a significant issue.
Q. And you are aware, Doctor, that apart from the dyspareunia and the interference with sexual activity, pelvic organ prolapse symptoms can include pelvic pain or voiding problems?
A. It can and -- yeah, the voiding problems, in severe cases, it can do that. The other aspect of it you said is --
Q. Pelvic pain?
A. Pelvic pain, yeah, that can -- the usual thing I get is described as an aching, even a low back pain because of the prolapse.
Q. And when we say voiding complaints, that would include difficulty urination?
A. In severe cases of anterior prolapse, yeah, you can trouble as far as emptying the bladder. I very rarely see that but it has been described, yes.
Q. And so as you and I just went over for the jury a variety of complications that a woman can experience from a pelvic organ prolapse can result in a woman seeking out medical care to get that repaired,

Page 211

correct?
A. That is correct, yes.
Q. And, in fact, I think you've told us before pelvic organ prolapse is a condition for which women have sought treatment for thousands of years?
A. I think I stated before as long as women have been having babies, they have been having problems with this, yes.
Q. And as long as there have been doctors who are concerned about caring for women, doctors have been trying to come up with good, satisfactory ways to treat a woman's pelvic organ prolapse, correct?
A. That is correct, yes, sir.
Q. And I think you told us that the treatment options for pelvic organ prolapse include conservative measures and surgical options as well, right?
A. Correct.
Q. One conservative measure you told us about was a wait and see approach?
A. Correct, observation, yeah.
Q. Another -- you used this term -- a pessary, right?
A. That's correct.
Q. And I think you told us that was a plastic

Page 212

device that can be inserted into the vagina as a way to sort of prop up the falling organ?
A. Correct.
Q. Now, pessaries are not appropriate for all patients, you agree with that, right?
A. They might not work in all patients. As far as it being appropriate or not, in the rare case of some vaginal erosion, you wouldn't want to put anything in there. I would think the better statement would be they don't work in all patients.
Q. Fair enough. So the distinction you are drawing is a doctor, when considering how to treat a woman with a prolapse, would include a pessary on the list and then make a decision whether it's a good or bad idea here?
A. That would be fair to state, yes.
Q. Some women don't want to use a pessary, right?
A. Correct.
Q. If a woman receives a pessary, she has to be followed up periodically with her physician, correct?
A. Correct, yes.
Q. You have seen reports of vaginal discharge

Page 213

with a pessary, right?
A. That is correct.
Q. You've seen reports of vaginal odor with a pessary?
A. Correct.
Q. There have been reports of ulceration with pessaries, correct?
A. That's correct.
Q. Obviously, that can lead to pain for the patient?
A. It could be, which you take out the pessary and that resolves itself.
Q. There can be bleeding associated with a pessary?
A. Along, yeah, with vaginal erosion that can happen.
Q. Tissue erosion?
A. It can, all those things, yeah.
Q. The symptoms that we've just described that can result from a pessary may lead a woman to discontinue the use of the pessary, right?
A. That is correct, yes.
Q. Of course, it's reasonable to believe that or to expect that a woman who has had a problematic

Page 214

experience with a pessary that caused her complications, she would be less likely to accept that treatment again in the future?
A. I agree with you.
Q. And you don't actually even deal with pessaries yourself in your clinical practice, correct?
A. Yeah, you're correct. We discuss it. If we feel a patient is a good candidate for it, I send them to my GYN colleagues.
Q. We've been discussing a pessary as one of the conservative ways to treat a prolapse but you would agree that most of the time prolapse cases treated conservatively, the condition does not get better?
A. Yeah, though it -- prolapse does not frequently or rarely would get better. It usually stays the same or worsens.
Q. So you would agree, Doctor, with the statement that absent surgery, pelvic organ prolapse tends not to improve?
A. In general, that would be a fair statement.
Q. Now, there have been multiple types of surgeries trying to fix the problem of a prolapse, right?

Page 215

A. Correct.
Q. Some of those surgeries have been around a long, long time?
A. That is correct.
Q. And over the years some surgeries have been more effective than others?
A. Correct.
Q. Different doctors use different approaches depending on their own experience, skill level, their comfort level as to which surgical option that physician prefers, correct?
A. That's correct.
Q. Transvaginal mesh was developed as one of the options for doctors to use to treat women with pelvic organ prolapse?
MR. SLATER: Objection.
THE WITNESS: Correct, yes.
BY MR. ISMAIL:
Q. One of the surgeries you described for us earlier as one of the surgical options was native tissue repair surgeries; do you recall making reference to that?
A. Correct, that's traditional colporrhaphy, yes.

Page 216

Q. So there are different types of colporrhaphy procedures depending on which type of prolapse the patient has, correct?
A. Dependent upon the anatomical location, yes.
Q. So if --
A. Well, it's only going to be anterior and posterior, that's the only colporrhaphies.
Q. So anterior being a bladder prolapse?
A. Correct.
Q. And posterior being a rectal prolapse?
A. Correct.
Q. And the idea behind a colporrhaphy is that the surgeon is using the patient's own tissues and sutures as a way to prop up the descending organ, correct?
A. Yeah, you are correct, it's a plication or a bringing together of the tissues that have separated or thinned.
Q. One of the perceived problems with that type of surgery, the native tissue surgery, going back to say the 1990s, was that there were recurrences or failures of that type of surgery, correct?
A. Yeah, recurrence or failure can happen

Page 217

with any surgery, it can happen with those, yes.
Q. And particularly, Doctor, my question is more of a historical one. If you go back to the period of time in the 1990s there was a feeling in the medical community that native tissue surgeries for treatment of prolapse had a high rate of failure?
A. I think the best way to say it is we didn't want to have any failure. I was a resident during that time, in training. We didn't want to have any failure so there was the pursuit of trying to find something that had a less failure rate.
Q. The -- historically the assessment of what was a success or a failure focused on the anatomical outcome, correct?
A. Historically that was one of the main features of it, yes.
Q. And I think you described for us today that the success or failure of a prolapse surgery can be measured either anatomically or by a review of the patient's symptoms, correct?
A. It depends, yeah. When you are doing a study you are going to say this is an anatomical study or a functional study or both. But, yeah, there's different ways of looking at it, but the tradition --

Page 218

now you've got to look at function.
Q. And my question wasn't just in the context of a study but also with regard to a doctor treating a patient, the doctor can and will assess anatomic function and can and will assess symptomatic function, correct?
A. Yeah, you can assess it but what you care about is the patient happy or not.
Q. And when we're talking anatomic recurrence of a prolapse, we mean the surgeon can -- in examining the patient, has assessed that the prolapsed organ has redescended to a certain degree following the surgery, correct?
A. That's part of the assessment, yes.
Q. And anatomic recurrence of the prolapse was a concern because it exposed women to the risk of incurring the same prolapse symptoms again, right?
A. Possibly, yes.
Q. And I think just so we're focusing on the period of time before Prolift® was developed, you would agree that historically anatomic recurrence was a concern to doctors treating women with pelvic organ prolapse?
A. I think initially, yes, you are right and

Page 219

then there became the shift overlooking at is the happy patient, quality of life.
Q. It was the recurrence concern that led doctors and surgeons to begin to experiment with the use of mesh to reinforce the pelvic floor, correct?
A. I think that's fair, yes.
Q. And at the time that Prolift® was under development you were familiar with the reports that nonmesh surgical repairs of prolapse had failures up to 30 to 40%?
A. Yeah, but, again, you got to look at what paper that is. Are they looking at stage 2 being abnormal, you know, there is a debate now that is within the realm of normal, so you have to look at the specific studies, but those reports are out there. I don't agree with them and we don't now agree with it, but I agree there are reports out there.
Q. So, again, this question is going back to the time before the Prolift® was developed, you're aware that there was a concern that there was an unacceptably high failure rate with native tissue surgeries?
A. I think some people had those. Again, I didn't have those concerns.

Page 220

Q. You were in training at the time, right?
A. Yeah. Well. Depends when you are talking.
Q. 1990s?
A. Yeah, '93 to '99 -- '93 to 2000.
Q. And some of the work that was done that assessed the success or failure of native tissue surgery was actually under the direction of the NIH, right?
A. Correct, you know, A lot of people were looking at it, yes.
Q. And so by that I mean there were researchers who were concerned about the failure rate of native tissue surgery outside of industry or manufacturers, that's fair to say?
A. Oh, yeah, I mean, doctors were very concerned about it. We wanted to get that recurrence rate down to zero.
Q. So one of the initial uses of mesh in the treatment of pelvic organ prolapse was through an abdominal surgery, correct?
A. The sacrocolpopexy has been around a long time, yes.
Q. And I think you told us earlier that the

Page 221

mesh used in Prolift® is a polypropylene mesh?
A. Correct.
Q. And mesh used in the abdominal sacrocolpopexy also is polypropylene mesh, correct?
A. It can be and the one I use is.
Q. Most often the mesh used in abdominal sacrocolpopexy, is it polypropylene mesh?
A. I can't speak to everyone out there, some people have used cadaveric tissue and that is becoming more common now but it's -- again, I don't know. I would suspect there's more polypropylenes than anything else.
Q. Polypropylene has been used in surgical procedures for decades, correct?
A. That is correct.
Q. Polypropylene is used in sutures, some sutures, correct?
A. That is correct.
Q. And the use of polypropylene sutures goes back many decades, true?
A. Correct.
Q. You indicated that polypropylene was used in a hernia mesh; do you recall saying that earlier?
A. That's correct.

Page 222

Q. The use of polypropylene hernia meshes goes back many decades as well, correct?
A. It's been around a long time, yes. Has a well-established track record.
Q. Historically the abdominal sacrocolpopexy was an open abdominal procedure, correct?
A. That is correct.
Q. Where a long incision would be made into the abdomen?
A. Well, it depends how you define long. From the umbilicus to -- the belly button to the pubic bone, so roughly -- however long that is.
Q. And the surgeon would then have to navigate through the abdominal cavity and work their way to place the mesh to repair the organ that was being prolapsed?
A. Correct, it was stated in a very colorful way, navigate through. Just go down there and get the job done, but, yes, you are right.
Q. And you don't mean to minimize the invasiveness of an open abdominal mesh repair of prolapse, are you, Doctor?
A. No. It's -- you know, there is an abdominal incision made, there are risks with that and

Page 223

so I'm not going to say it's a minimally invasive nature compared to doing it robotically, no.
Q. The abdominal sacrocolpopexy performed with mesh has had a high success rate for vaginal vault prolapse, correct?
A. It would be arguably the best, yes.
Q. The use of polypropylene mesh in abdominal sacrocolpopexy was viewed as a advancement in the surgical treatment of pelvic organ prolapse, correct?
A. I think that's correct. The studies going back looking at cadaveric tissue found a higher failure rate with it. So polypropylene, through the abdominal route, has been shown with good and acceptable risk versus benefit ratio.
Q. The abdominal surgery for the placement of mesh can be a complicated surgery?
A. Well, I don't know what you mean by -- I mean, I do it routinely, overnight stay in the hospital and they're home. So complications can occur, I suppose.
Q. The open abdominal placement of mesh can be a surgery that lasts many hours?
A. Better not. I do it hour and 15 minutes, two days -- last Friday.

Page 224

Q. Can it?
A. Well, not in my hands. I can't speak for other surgeons. I don't mess around.
Q. Do you agree that transabdominal surgery is associated with increased morbidity compared with vaginal repairs?
A. You have to define what you mean by vaginal repairs. Transvaginal nonmesh repairs traditionally have been associated with a lower morbidity, perioperative morbidity, but, again, it has to be balanced as far as with success, but now if you are talking about Prolift® meshes, that becomes a different story, which we'll get to later I'm sure.
So I think it's fair when you compare abdominal, transabdominal with an incision versus transvaginal without meshes, it's fair to say that the transvaginal without mesh would be a less morbid procedure.
Q. When you say "morbid" in that context, what do you mean?
A. Perioperative, intraoperative complications.
Q. Perioperative means during the procedure?
A. Perioperative -- well, perioperative means

Page 225

just around the time of the surgery.
Q. And due to the morbidity of the open transabdominal procedure, many patients were unable to tolerate that procedure, correct?
A. Some patients wouldn't. I mean, my practice is not many, but some don't want to undergo that big of a surgery.
Q. So going back to this period in the 1990s and the early 2000s, researchers were reporting high -- higher than desirable failure rates for nonmesh repairs, correct?
A. Done through the vagina.
Q. And there was a recognition that the use of mesh through the transabdominal route resulted in a more stable or durable repair, correct?
A. Correct.
Q. And there was some concern or desire to lower the morbidity of the transabdominal procedure, correct?
A. Correct.
Q. And so you agree, Doctor, it was a worthwhile research objective to investigate whether improvements could be made to the surgical devices and techniques for the treatment of pelvic organ prolapse,

correct?
A. I am an advocate of innovation so if there's a way of making something better, I am for it, but it has to be a safe advancement.
Q. So you agree that even today it's still a worthwhile research objective to find improved ways to surgically repair pelvic organ prolapse, correct?
A. Until we get to the day of 100% success and no complications, it's a worthwhile venture.
Q. Scientists, whether they're affiliated with universities or manufacturers or whatever, always are looking for ways to improve the surgical treatment of pelvic organ prolapse, correct?
A. I can't agree with that, no.
Q. Then let me rephrase.
The research into the improvements of the surgical techniques for pelvic organ prolapse has been going on several decades?
A. Yeah, longer than that, yes, I agree.
Q. Fair enough. You agree that it was admirable to search for a way to make pelvic organ prolapse recurrence -- withdrawn. Let me start over.
You agree it's admirable or it was admirable to search for a way to make the surgical repair of pelvic

organ prolapse result in fewer recurrences of the prolapse?
A. I feel it is a very worthwhile endeavor -- if you want to use the word admirable that's okay -- to make a more efficacious and safe prolapse repair.
Q. Now, we've already discussed the hypothesis that polypropylene mesh might allow for a more stable or durable repair of the prolapse, correct?
A. Well, depends if you are talking about transabdominal or transvaginal.
Q. Well, the hypothesis that led to the use of mesh in transabdominal surgery as resulting in a more stable repair, that was actually borne out, correct?
A. That's true.
Q. And so you agree that that was a legitimate hypothesis?
A. Legitimate hypothesis?
Q. If you are having trouble with that word, I'll rephrase.
A. Yeah, let's -- can you use a different word?
Q. The research initiative that resulted in the use of mesh for the abdominal surgery to repair

pelvic organ prolapse, that turned out to be a worthwhile and useful innovation in the treatment of patients who have pelvic organ prolapse?
A. I think as we can state right now the use of transabdominal polypropylene meshes has improved the outcome as far as we know right now.
Q. There was another hypothesis that the use of a transvaginal mesh could cut down on the morbidity of the abdominal surgeries, correct, that was the idea at the time?
A. Well, the idea at the time was to blend meshes and avoid the potential issues of going through the abdomen, so that was their theory, but I can't speak to exactly what they were thinking. I wouldn't know.
Q. Let me just say it this way, Doctor, the reason and purpose behind the development of transvaginal mesh was to reduce the morbidity seen with the abdominal sacrocolpopexy approach, true?
A. That would be part of it.
Q. And you agree that that was a laudable goal, to search for a different way of doing the surgical procedure?
A. I will never criticize the pursuit of

innovation in improvement, as long as it's balanced and thought through.
Q. When the Prolift® was developed it was not the first time that surgeons implanted mesh transvaginally, correct?
A. No, mesh has been done -- not mesh, excuse me -- foreign body synthetics, manmade products have been used transvaginally at other times, yes.
Q. And even before the Prolene was developed, polypropylene mesh had been implanted transvaginally, correct?
A. Before the Prolift, yes, the Gynemesh® had been used, yes.
Q. And even before Gynemesh® transvaginal mesh was used in surgery for other applications, correct?
A. Well, you have to show me exactly what you are talking about. I mean, Marlex has been used, other products have been used, it had unacceptably high complication rates. I have to see exactly what product you are talking about.
Q. I'll rephrase.
Prior to the use of transvaginal mesh in pelvic organ prolapse, was transvaginal mesh used for

Page 230

treatment of other conditions?
A. Transvaginal mesh for other conditions? Oh, are we talking about like incontinence or something like that? I guess, yes, for incontinence.
Q. Before you were -- withdrawn.
Now, with respect to the Prolift® you're aware that there have been several randomized controlled clinical trials comparing the use of Prolift® to other surgical approaches, correct?
A. Yes, there have been quite a number of studies out there, yes.
Q. So I don't think this has been done yet for the benefit of the jury, but let's just explain what randomized controlled clinical trials are, okay?
A. Okay.
Q. So there's a variety of ways that scientists can undertake research, correct?
A. Yes.
Q. Sometimes you will have animal research, sometimes you have laboratory research and sometimes you have clinical research?
A. Correct.
Q. And one form of clinical research is what we call randomized controlled clinical trials?

Page 231

A. That's correct.
Q. And in randomized controlled clinical trials you have two groups of patients that you try to have evenly matched?
A. Yes.
Q. And one group receives a treatment method and a different group either receives no treatment or sometimes a different treatment method?
A. Correct.
Q. And then the researchers follow those patients over time and see how they do both from a effectiveness perspective and a safety perspective?
A. Correct.
Q. And you would agree that randomized controlled clinical trials are some of the best quality research that can be done on a surgical procedure?
A. They can be if the study is run correctly, but they're one part of the information that's available.
Q. Now, there have been many randomized controlled studies done on the safety and effectiveness of Prolift®, correct?
A. Again, there have been studies done. There have been a number done.

Page 232

Q. And there have been randomized controlled clinical studies done comparing the Prolift® to the older native tissue surgery, correct?
A. Correct.
Q. And that's something you looked at before you came to talk to the jury about your opinions on Prolift®, correct?
A. Correct.
Q. Some of those randomized controlled clinical trials looked to the relative success of the native tissue surgery compared to the Prolift® in repairing the woman's prolapse, correct?
A. As far as anatomical repairs, yes, that was looked at.
Q. And many of those high quality randomized controlled clinical studies demonstrated that women treated with a Prolift® experienced a lower rate of anatomical recurrence compared to the native tissue?
A. Well, again, you said "many". There are some that show anatomy success, there are also many that show equivocal results, but, again, anatomy is not what we look at.
Q. Well, Doctor, you're aware that there have been several studies done that -- and again we we're

Page 233

talk -- withdrawn.
When we're talking anatomic success we're talking has the surgery been effective in returning the woman's internal organs to a more anatomically correct position?
A. That's what anatomical studies are about, but the woman doesn't care about that.
Q. And --
MR. ISMAIL: Move to strike as nonresponsive.
BY MR. ISMAIL:
Q. Can you answer the question I asked, Doctor?
A. I thought I did.
The anatomical studies look at the anatomy of the patient, not the psyche.
Q. Thank you.
And several randomized controlled clinical trials have demonstrated that Prolift® has a -- results in a better anatomical fix of the prolapse compared to the native tissue surgery, true?
A. Well, number one, I'd have to see those studies. Number two, we have to talk about which compartment they're talking about, anterior --

Page 234

Q. I appreciate the distinction and I'll clarify.
When we talked about -- you've used the times anterior and posterior at times in your testimony?
A. Right.
Q. And just, again, because those aren't terms that laypeople often use, just to define them, anterior we're talking about, essentially, a bladder prolapse, correct?
A. Correct.
Q. And a posterior, we're talking about a rectal prolapse?
A. Correct.
Q. So let me focus on the anterior prolapse, okay.
Many randomized controlled clinical trials have demonstrated that surgery with a Prolift® results in a better anatomical repair of an anterior prolapse compared to a native tissue surgery, true?
A. Well, I'd have to somewhat disagree. There are going to be some studies out there that show better anatomy, but I have to look at those specific studies, but they also show equivocal. So, again, how do you want to define many? You know, say 100, five,

Page 235

one? So I just have to see.
Q. Okay. How many are you aware of?
A. I have reviewed 450 manuscripts, I can't, off the top of my head, come up with them.
Q. Certainly, Doctor, you wouldn't dispute that Prolift® has been shown to result in a better anatomical repair of an anterior prolapse compared to a native tissue surgery?
A. You know, I've never really argued against anatomic repair, that's not an issue for me, it's the patient's quality of life is. So an anterior, you can find studies that show better or equivocal in anatomic repair. Posterior and apical, it's a different story.
Q. Agree that nobody -- you agree that nobody, including you, would dispute anatomic success with mesh is very strong?
A. I would agree with you that it has been shown to work, again, but that's not the issue that I'm concerned about in our patients.
Q. Thus far, Doctor, we've been talking about anatomic success of the surgery and you, as you just did, want to make reference to another measure of success and that is symptomatic --
A. Correct.

Page 236

Q. -- outcomes, correct?
A. You are correct.
Q. Symptomatic outcomes have been measured as well in some of these studies that we've discussed, correct?
A. Correct.
Q. Including in some randomized controlled clinical trials, correct?
A. Correct.
Q. Patients with a Prolift® surgery have demonstrated improvement in symptomatic results, correct?
A. Yes, that has happened, yes.
Q. Patients implanted with a Prolift® have demonstrated improvements in quality of life, correct?
A. That has been demonstrated, yes.
Q. You referenced earlier biologic or cadaver tissue being used in pelvic organ prolapse; is that right?
A. Correct.
Q. Surgical experience with those techniques revealed the biological or cadaver tissue in sacrocolpopexy had a high failure rate?
A. With specifically sacrocolpopexy it --

Page 237

several different studies have shown it was not as strong.
Q. So the biologic tissues that you referenced in your testimony are not as strong as the polypropylene mesh for repair, right?
A. Well, we're talking about transabdominal. Transabdominal I agree with you.
Q. Now, there were other polypropylene transvaginal mesh kits developed other than the Prolift®, correct?
A. That is correct.
Q. Developed by different manufacturers?
A. Correct.
Q. What are some of the other manufacturers who have developed polypropylene transvaginal mesh kits for prolapse repair?
A. Coloplast, AMS, Bard, Boston Scientific, and there may be some more in there. Those are the ones I see the most.
Q. And do you believe, Doctor, you have done a comprehensive review of the scientific literature on the randomized controlled trials involving transvaginal mesh for all these products?
A. I reviewed the PubMed, which is the

Page 238

world's largest search engine, 24 million articles I recall, and I have reviewed -- you know, it's as comprehensive as I'm going to be able to get.

Q. Can you confirm, Doctor, that the Prolift® has been studied in more randomized controlled clinical trials than any other transvaginal mesh used in prolapse repair?

A. I don't doubt that, no.

Q. Doctor, you made some comments earlier about the amount of clinical trials that had been done on the Prolift® at various points in time; do you recall that in your testimony?

A. I don't recall that.

Q. You don't?

A. I'm sure I've been asked that question, yes.

Q. One of the procedures that you described that you are aware of at your institution is the robotic abdominal sacrocolpopexy?

A. Correct.

Q. Now, at the time that you participated in that surgery, when you first started doing that surgery, you were not aware of any randomized controlled trial anywhere in the world, correct?

Page 239

A. I and my colleague were the first in the world to do it, so there's no way of having a randomized controlled trial.

Q. And even today there is not a randomized controlled clinical trial on the use of robotic abdominal sacrocolpopexy for the treatment of prolapse, correct?

A. No, there's been laparoscopic versus robotic, I have reviewed those papers, those papers are out there.

Q. When did those come out?

A. Oh, those came out years ago.

Q. When?

A. I reviewed -- I have no idea. I reviewed them, they asked me to review it because of my expertise so there are going to be those trials out there. I don't -- right now as I sit here can't think of one robotic versus open.

Q. Let me -- by the way, with respect to the robotic procedure you just described, you don't operate the robot in that procedure?

A. No, my colleague does.

Q. See how we're doing on time, Doctor.

Now, with respect to this robotic abdominal

Page 240

sacrocolpopexy procedure that you participate in, do you use polypropylene mesh?

A. Yes.

Q. And you continue to use mesh in that procedure, correct?

A. For that specific procedure, yes.

Q. And you have for the last ten years?

A. Longer than that. Probably 2003 with the robotically and then prior to that was transabdominal.

Q. The mesh that you use in your practice is called InterPro?

A. InterPro by AMS.

Q. The InterPro mesh that you use in your practice you believe is a large pore mesh, correct?

A. No.

Q. Do you believe the InterPro mesh that you use in your clinical practice is a lightweight mesh?

A. No. It would probably be -- I would have to look up the specific numbers, it would probably be a moderate weight. I don't recall the exact numbers. They're quite similar to Gynemesh®.

MR. ISMAIL: I'm going to mark this as Exhibit 1 and we'll remark it for trial purposes later.

Page 241

(Document marked for identification as Deposition Exhibit No. 1.)

BY MR. ISMAIL:

Q. First of all, Doctor, you indicated in your last answer that the mesh you use in your clinical practice is a polypropylene mesh that's very similar to the mesh that's used in the Prolift®, correct?

A. I didn't say very similar. I said it's similar to.

Q. Okay. I will rephrase.

You agree, Doctor, that the mesh you use in your clinical practice is a mesh that's very -- withdrawn.

The mesh you use in your clinical practice is similar to the polypropylene mesh used in the Prolift®, correct?

A. Correct.

Q. I've handed you what we've marked for identification as Exhibit 1.

Is this an article that you are listed as an author on?

A. That's correct.

Q. And it is on the use of robotic sacrocolpopexy in prolapse repair?

Page 242

A. That is correct.
Q. And in this article, Doctor, do you tell the medical community what materials you use in the procedure?
A. Yes, we do.
Q. And do you describe the polypropylene mesh that you use in your procedure?
A. Yes.
Q. If you turn to Page 2 of the article, in the left column.
A. Yes.
Q. And in there you inform the medical community on the technique for this robotic procedure that you are describing in the article, right?
A. That is correct, yes.
Q. And if you work your way down in that left column, above the anatomical cartoon there, you make specific reference to the polypropylene mesh that you use in your procedure, right?
A. That is correct.
Q. Do you say, quote, Next, a Y-shaped large pore, lightweight polypropylene graft (InterPro; American Medical Systems) is sutured into the vagina?
A. That's what we state, yes.

Page 243

Q. So you, in your article that you published to the medical community, describe InterPro as a large pore lightweight polypropylene mesh, correct?
A. That is correct.
Q. The date of this article, sir, was -- is what?
A. 2015.
Q. In fact, it was submitted and received by the journal on May 26, 2015, correct?
A. That's correct.
Q. That's some -- that's several years after you had begun work already on behalf of the plaintiff lawyers in this case?
A. That is correct.
Q. It's after you formed your opinions about Gynemesh®, correct?
A. That's correct.
Q. So when you published for the medical community -- withdrawn.
You published in the medical community that InterPro, the mesh you use, is large pore, right?
A. That's correct.
Q. You talked about pore size with Mr. Slater several times earlier today, correct?

Page 244

A. Correct.
Q. You agree that the porosity of the mesh used in Prolift® is similar to InterPro, correct?
A. Well, Prolift® is only a transvaginal procedure. So transvaginal versus transabdominal, we're talking different procedures there.
MR. ISMAIL: Move to strike as nonresponsive.
BY MR. ISMAIL:
Q. Do you remember my question, Doctor?
A. No, I do not.
Q. I'll restate it.
The polypropylene mesh you use, InterPro, has a porosity similar to Gynemesh®?
A. That is correct.
Q. The porosity of Gynemesh® is similar to the mesh used in the Prolift® kit, correct?
A. Should be the same.
Q. So the answer to that is yes?
A. Yes.
Q. And you described your -- the mesh you use as large pore, correct?
A. That is correct.
Q. You also described the mesh you use as

Page 245

lightweight, correct?
A. Correct.
Q. The mesh -- the polypropylene mesh you use is -- has a similar weight to the Gynemesh®, correct?
A. That is correct.
Q. And the Gynemesh® would have a similar weight to that used -- the mesh used in the Prolift® kit, correct?
A. That's correct.
Q. By the way, Doctor, do you know whether the mesh you use in your practice has bi-directional elasticity?
A. It doesn't.
Q. It does not?
A. No.
Q. So the missing characteristic of bi-directional elasticity hasn't stopped you from using InterPro mesh in your practice, right?
MR. SLATER: Objection, lack of foundation, mischaracterization of direct.
THE WITNESS: Because I'm using it through an abdominal route, just like Gynemesh® is still available for abdominal route, so you can't compare the two surgeries.

Page 246

BY MR. ISMAIL:
Q. I haven't compared anything, Doctor. My question was different. Do you remember it or do you want me to restate it?
A. Please restate it.
Q. The missing characteristic of bi-directional elasticity has not stopped you from using InterPro mesh in your procedures, correct?
MR. SLATER: Objection, mischaracterization and lack of foundation.
BY MR. ISMAIL:
Q. You can answer the question.
A. Yeah, I can't give you -- I think it would be unfair to give you a yes or no. I have to say I'm doing it through a different route.
If I were doing it through the vagina, absolutely. Through the abdomen I have not seen that issue.
MR. ISMAIL: Move to strike as nonresponsive.
BY MR. ISMAIL:
Q. Again, it's not -- I have not compared it to transvaginal surgery or not. It's a very simple question, Doctor.

Page 247

A. And I feel I need to explain it to be accurate.
MR. ISMAIL: Move to strike as nonresponsive.
BY MR. ISMAIL:
Q. Do you have my question in mind?
A. No, I still do.
Q. Well, let me restate it, just for the benefit of the record.
The mesh that you use in your clinical practice you believe does not have bi-directional elasticity, correct?
A. Correct.
Q. And that has not stopped you from using that mesh in your abdominal sacrocolpopexy procedure, correct?
A. As you are specifically stating there, you are correct, through the abdomen, I agree with you.
MR. ISMAIL: Okay. When did we start, 12:40. Everyone doing okay?
THE WITNESS: Can I get something to drink?
MR. SLATER: Take five minutes.
MR. ISMAIL: Sure.

Page 248

THE WITNESS: I can get something. I'm out of fluid here.
THE VIDEOGRAPHER: The time is 1:47 and we are off the record.
(Brief recess.)
THE VIDEOGRAPHER: The time is 1:53. And we are back on the record.
BY MR. ISMAIL:
Q. Doctor, I want to turn now to something in your prior testimony regarding the instructions for use that you offered.
Now, prior to being retained by the plaintiff lawyers, you had never before looked at a manufacturer's internal standards for what to include in the instructions for use, correct?
A. That is correct.
Q. And if we were to consider your articles that you've published in the literature, you've never before published on the standards that a manufacturer uses for instruction for use, correct?
A. Correct.
Q. With respect to the Prolift® instructions for use, before you got involved in this case you had never even read the Prolift® instruction for use,

Page 249

correct?
A. Well, again, I know I did not read the Gynemesh®, I know that, but I visited the booth at Ethicon and, as I recall, looked at the IFU, looking at it online. I can't recall specific dates.
Q. One moment, Doctor.
MR. SLATER: If you are going to pull a transcript or something just let me know so I can look for it. Is it the Bellew transcript or something else?
MR. ISMAIL: This will be the witness' deposition. I have a copy for you if you'd like.
MR. SPECTER: That would be great. Thank you.
MR. SLATER: Yeah, sure. Splendid.
MR. ISMAIL: I'll give one to you too in a minute, Doctor.
Doctor -- ready to proceed everyone? I'll give you page and line when we get there. Adam.
MR. SLATER: What's that?
MR. ISMAIL: Ready to proceed?
MR. SLATER: Oh, yeah. I figured you

Page 250

would tell us the page and line before you --
MR. ISMAIL: I will.
BY MR. ISMAIL:
Q. Doctor, you referenced earlier you gave a deposition in this case, correct?
A. Correct.
Q. And when you gave that deposition you took an oath to tell the truth, correct?
A. That's correct.
Q. Same type of oath that you took today?
A. Correct.
Q. And you understood when you took that oath that it was as if you were in court?
A. Correct.
Q. There was a court reporter there who was taking down the questions that were asked and the answers that you gave, correct?
A. Correct.
Q. I ask, Doctor, if you turn to Page 391 of your deposition?
MR. SLATER: Just one thing for the record, I just -- I'm looking what you asked, just -- well, actually, I'll withdraw it. You go ahead. What page did you say?

Page 251

MR. ISMAIL: 391, Line 1.
BY MR. ISMAIL:
Q. Doctor, were you asked this question:
"Before becoming engaged in this litigation, had you ever reviewed the Prolift® instructions for use?"
Is that the question you were asked?
A. Before I -- you're on Line 9?
Q. Line 1.
A. Oh, Line 1. I'm sorry.
Q. Let me begin again.
A. I'm sorry.
Q. Doctor, were you asked this question and did you give this answer:
"Question: Before becoming engaged in this litigation, had you ever reviewed the Prolift® instructions for use?
Answer: No, I had not."
Was that your sworn testimony, sir?
A. That's what I gave then, yes.
Q. Before being involved in this litigation had you ever read the instruction for use for Gynemesh®?
A. Gynemesh®, I don't recall ever reading

Page 252

that, no.
Q. So when you discussed earlier that you had used instructions for use in your interaction with residents, do you recall giving testimony to that effect?
A. Yes.
Q. That was a more general statement regarding how using instructions for use in other contexts besides the Prolift®, correct?
A. Correct.
Q. So you never taught or interacted with residents before this litigation on the Prolift® instruction for use, correct?
A. I think that would be fair. We looked it up online, what was available, but it was not a formal teaching. It was more of an idea of what happens with the procedure.
Q. Now, you're not suggesting, Doctor, that the instruction for use is the only way surgeons obtain information about the surgeries they perform, are you?
A. It is not the only way. It is one of the ways.
Q. Surgeons obtain information pertinent to surgery from numerous sources, right?

Page 253

A. Possibly. It depends upon the surgeon.
Q. So surgeons obtain information relevant to surgery from their own education, right?
A. Well, I can't speak for all surgeons out there. Everybody is different. There are different levels of surgeons and different levels of motivation and different levels of quality delivered, so I can't speak for everybody.
For me, at an institution I am in and the ability to travel all over the world for meetings, the IFU takes less of a meaning. If I'm out in the middle of USA somewhere, they become more important. So, again, I can't speak for everybody.
Q. Let me rephrase.
You are aware, Doctor, that surgeons can rely on their education and training to understand the risks and benefits of surgeries that they perform?
A. They can, yes.
Q. Surgeons can rely on the medical literature to understand the risks and benefits of the surgeries they perform?
A. That is another avenue for it, yes.
Q. Surgeons can look to medical conferences as another source of information about the risks and

Page 254

benefits of surgeries they perform, correct?
A. Possibly, if they're able to go to the meetings, yes.
Q. Surgeons can rely on their own clinical experience when understanding the risk and benefits of the surgeries they perform, correct?
A. Possibly, if they performed the procedure before.
Q. Surgeons -- have you ever heard -- withdrawn.
Have you ever heard of a surgical guide?
A. Yes.
Q. Surgical guides have been prepared in addition to instructions for use, correct?
A. That's a generic statement for everything, but there are surgical guides available for some procedures.
Q. And surgeons can look to a surgical guide or a monograph to learn information about the risks and benefits of a surgery they can perform?
A. If that's available, they can do that, yes.
Q. When you were on direct examination with Mr. Slater you did not discuss the surgical guides or

Page 255

monographs with Prolift®, correct?
MR. SLATER: Objection.
THE WITNESS: I wasn't asked.
BY MR. ISMAIL:
Q. So the answer to my question is correct?
A. Yes, you are correct.
Q. Mr. Slater asked you some questions about design standards; do you recall that?
A. Correct.
MR. SLATER: Objection, mischaracterization.
BY MR. ISMAIL:
Q. Prior to being retained by the plaintiff lawyers in this case had you ever been aware of the internal design standards that a manufacturer uses to develop a new surgical device?
A. Specifically that? I mean, I have patents of my own on a product, was involved in the early stages of designing of a product as a resident, but as you narrow it down there are specific industry standards, my level of knowledge would be not as much as it is now.
Q. When you say "not as much as it is now," you mean through your work as a paid witness on behalf

Page 256

of the plaintiffs, right?
A. Yes and no to that. It's through my work, yes, definitely through the litigation, but also as my internal curiosities, what are the standards industry is required to do, because I'm a surgeon implanting devices and I kind of want to know what really goes on behind the scenes.
Q. Okay. So if we focus on the period of time as of when you were first retained by the plaintiff lawyers, you would agree that you did not have experience with the internal design standards a manufacturer uses to develop a new surgical device, correct?
A. Well, no, if you look at my CV, I was involved in transurethral enzymatic ablation of the prostate, which I worked with a researcher and the founder of the company and working with the FDA as far as getting it approved, that's when I was a resident.
I worked with the design of a new artificially designed urinary sphincter for males by Timm, T-i-m-m is the name of him, so we were working on the standards with the companies, and then my own patent. And so it depends how extensive a level of knowledge.
I'm not an FDA -- I'm not employed by the FDA.

Page 257

I didn't design any FDA regulations but I have working knowledge of what would be required.
Q. Let me rephrase my question. And I'm talking about internal --
MR. SLATER: Can I -- I'm sorry, I just got a text and I have to call somebody back really quick. I don't want to -- if it's a bad spot, I just -- it has nothing to do with work.
MR. ISMAIL: Off the record.
MR. SLATER: Thanks.
MR. ISMAIL: Sure.
THE VIDEOGRAPHER: The time is 2:03 and we are off the record.
(Brief recess.)
THE VIDEOGRAPHER: The time is 2:07 and we are back on the record.
BY MR. ISMAIL:
Q. Doctor, let me rephrase my prior question to make it more specific.
Prior to being retained by the plaintiff lawyers in this litigation you had no experience on the internal design standards a manufacturer uses for the development of a new surgical device for treatment of pelvic organ prolapse, correct?

Page 258

A. I don't know. I would have to say that is only partially correct. As I mentioned previously, as far as my experience designing, as far as the transenzymatic ablation of the prostate, which was going through the FDA, we had FDA people come in, working in with them, the -- an artificially made sphincter for male incontinence with Dr. Timm, working and designing to the point of implanting in humans. And then with my patent, working with it. So those are all looking at safety, complications, ramifications.

MR. ISMAIL: Move to strike as nonresponsive.

BY MR. ISMAIL:

Q. Doctor, I'm not intending to ask anything about the FDA in my question, okay?

A. Okay.

Q. And you agree you are not an FDA expert, right?

A. I know what the standards they are going after, but I have not been employed by the FDA.

Q. So my question is very specific. I would ask that you only answer that question.

Prior to being retained by the plaintiffs in this litigation, you did not have experience on the

Page 259

internal design standards a company used to develop a new surgical device for pelvic organ prolapse, true?

A. Correct, I have never been an employee of any industry designing those issues.

Q. You earlier referenced, Doctor, the results of the TVM group in France; do you recall that, in the early development work on the Prolift®?

A. Yeah, we discussed two or three earlier studies.

Q. And you used the clinical study report in reference to the results of their success rate in the surgical use of the Prolift®, correct?

A. That is correct. As long as we're talking, it was Plaintiff Exhibit P0049, I assume we're talking about that one.

Q. Yes. And there were two arms to the TVM study, correct, one in Europe and one in the United States?

A. Oh, yes, yes. I'm sorry, I misunderstood, yes.

Q. And the data that you went over with Mr. Slater only related to the European TVM data?

A. That is correct, yes, not the American.

Q. Doctor, do you agree that pelvic organ

Page 260

prolapse surgeries -- withdrawn.

I think you told us earlier that all surgeries have risks associated with them, correct?

A. Well, all surgeries have their unique complications of it, severity, frequency, but surgeries can have some complications. Again, we have to define what surgery we're talking about.

Q. All right. Let's break it down.

All surgeries have sort of general risks related to surgery; anesthesia, potential infection, any time you are cutting tissue there is a potential risk, right?

A. Again, if you are talking about -- I'm not trying to be difficult, but I don't want to make a general statement. If we're talking about a skin biopsy in a dermatologist's office is different than cardiac surgery. So, again, that's why -- as a surgeon I have to define what I'm talking about, what procedure.

Q. Then we'll be specific.

With any pelvic organ prolapse surgery, even in the hands of the most skilled surgeon, there can be complications, correct?

A. Each surgery has its own unique

Page 261

complications, frequency and ability to treat those complications.

Q. And even yourself, Doctor, you would never guarantee a patient that a surgery you performed will be free of complications, correct?

A. You are correct.

Q. With any surgery in -- for pelvic reconstruction you have potential problems with bleeding, right?

A. It can happen. Certain procedures have higher risk, others have lower risk, but it can happen.

Q. Any surgery for pelvic reconstruction has risks associated with the use of anesthesia, correct?

A. Yeah, unless you are using a local anesthetic for biopsy, yeah, but, again, I don't like making a general statement. A procedure takes three hours versus one that takes ten minutes, there's different risks so everything is -- again, I don't want to be difficult by any means, but I'm a surgeon so we look at each specific procedure.

Q. The potential surgeries that could be used for repair of pelvic organ prolapse all carry a potential risk of infection, correct?

A. It depends. If you are using a foreign

Page 262

product, foreign body, the risk goes up. If you are not, I have -- I have, in my experience, never had a transvaginal procedure using native repair get infected.

Q. Do you have the -- I guess this is a different. Sorry, forgot to give you the other day but feel free to hold on to that. Not to add to your paper, Doctor, but here you go.

Doctor, I've handed you a transcript of testimony you gave on March 4, 2015; is that correct?

A. March -- you gave me March 3rd and March 4.

Q. I would like you to focus on March 4, please.

A. Okay.

Q. And you swore to tell the truth in that deposition, correct?

A. That is correct.

Q. I'm going to ask you to turn to Page 513 of your testimony.

A. Okay, I'm there.

Q. Line 21. Was this your question -- it was a question asked of you and was this your answer under oath:

Page 263

"And with any surgery, no matter what it is, you've got problems of -- potential problems with bleeding or infection or anesthesia problems, and so forth; correct?

Answer: In a general sense, yes."

Were you asked that question and did you give that answer under oath?

A. Yeah, and I agree with that answer still.

Q. And once you go on to the specific surgery at issue, there are potential complications with each specific surgery, correct?

A. Each surgery has its own unique complications.

Q. And that's true with surgeries in the pelvic floor, correct.

A. That is correct.

Q. There is a potential of serious injury with sacrocolpopexy, correct?

A. Well, it depends on when you are talking about injury to what? Again, that's not to be difficult but injury to the heart? No. Injury to the organs --

Q. To the patient?

A. To the patient in general, there is the

Page 264

potential for -- yeah, there is potential risk there.

Q. There is a potential risk of serious injury to the patient with a colporrhaphy procedure?

A. Not in my experience there hasn't been, but, I mean, again, I need to know what kind of complication you are talking about. I think we need to be clear.

Q. Doctor, I ask that you turn to transcript that I gave you earlier of your deposition taken on November 16th.

MR. SLATER: Objection.

BY MR. ISMAIL:

Q. First transcript I gave you, Doctor.

A. I have it, yes.

Q. Page 244.

A. 344?

Q. 244.

A. I don't have a 2 -- mine starts at 200 something.

Q. I'll give you that.

MR. SLATER: Stingy with the transcripts.

MR. ISMAIL: There you go.

MR. SLATER: That's what I heard about you.

Page 265

THE WITNESS: 244.

BY MR. ISMAIL:

Q. Yes, sir.

A. 244, I'm there.

Q. All right, Doctor. This, again, was sworn testimony you gave and the date of this was November 16, 2012; is that correct?

A. Correct.

Q. I'm sorry, 243, Doctor.

A. Okay. I'm there.

Q. Line 11.

"Question: Would you agree that there's a potential risk of serious --

Sorry, Line 7.

"Would you agree that there is a potential risk of serious injury with the sacrocolpopexy?

Answer: Yes."

Is that the question you were asked and answer you had given?

A. Yes, and I agree with that.

Q. Were you also asked is there "... a potential risk of serious injury with the sacrospinous ligament fixation?"

Your answer, "In a magnitude and frequency and

Page 266

intensity and delayed onset difference but, yes, there's a risk."

And then you were asked at Line 19:

"Would you agree that there's a potential risk of serious injury with a sacrospinous ligament fixation?

Answer: There is -- there is a risk there for serious injury, yes."

Were you asked that question and were you giving that answer under oath?

A. Yes, and I agree with that.

Q. And then on Page 244, what I really intended to direct you to in the first place, Line 2, would you agree that there's a serious risk with colporrhaphy?

What was your answer under oath?

A. "Yes."

Q. There are risks with hysterectomies, correct, Doctor?

A. Yes.

Q. All prolapse surgeries have -- carry the risk to other organs, correct?

A. Again, yes. We have to define what organ but --

Page 267

Q. Right, I'm not talking about the heart. I'm talking about the organs near the surgery that you're performing.

A. Correct, that -- that is an inherent risk with operating in that region, yes.

Q. There is an inherent risk of operating in that region of injuries to the nerves of the patient, correct?

A. Well, it depends what nerves you are talking about and it depends what prolapse surgery, that's why sacrospinous fixation I was very specific on, okay, or semi-specific.

The risks of sacrospinous fixation are comp -- significantly different than abdominal sacrocolpopexy or more significant than anterior colporrhaphy.

So, again, as far as nerve injury, it depends what nerves that we're talking about.

Q. Page 89 of the November 15, 2012 testimony.

A. Okay. I'm there.

Q. Line 21, were you asked this question:

"All prolapse surgeries have a risk to nerves?"

What was your sworn answer, Doctor?

A. You know, yeah, I see that, I say --

Page 268

Q. My question is what was your sworn answer, Doctor?

A. "Yes."

Q. Thank you.

All prolapse surgeries have a risk of pain, correct?

A. Again, I'd have to define the severity, the frequency, et cetera, but pain, to a certain degree, is a risk of all prolapse surgeries.

Q. That's inherent to the surgery, right?

A. That's inherent to that specific surgery, correct.

Q. All prolapse surgeries have a potential risk of pain with sexual intercourse, correct?

A. Yes. Again, as I'll state over and over, it depends upon the severity, the frequency, the progressive nature, but, yes, dyspareunia, pain with intercourse, can't happen with all of them, but they might not all have the severity of the pain.

Q. Page 90 of your testimony, Doctor, Line 2:

"Question: All prolapse surgeries have a potential risk of dyspareunia; correct?"

What was your answer, sir? Line 4.

A. Yeah, yes, I state it that there, as I've

Page 269

clarified today.

Q. All prolapse surgeries have a potential risk of pelvic pain, correct?

A. Again, dependent upon the procedure and the severity, they can be different, but they can all have pain, but, again, it depends upon that specific procedure.

Q. Line 5 of Page 90 of your testimony:

"Question: All prolapse surgeries have a potential risk of pelvic pain; correct?"

What was your sworn answer under oath, sir?

A. "Yes," with the clarifier I just did.

Q. In fact, persistent pain is a complication of prolapse surgeries other than the Prolift®, correct?

A. Again, that depends upon the severity and frequency. There's clarifiers.

Q. Turn to page -- of the November 16 testimony, Doctor. Line 21.

A. What page?

Q. I'm sorry. 454.

A. 454, Line 21, okay, I'm there.

Q. "Question: Persistent pain is a potential complication with other prolapse surgeries besides Prolift®, correct?"

Page 270

What was your sworn testimony under oath, sir?
A. Yeah, as I said --
Q. What was your testimony, sir?
A. I agree with that statement, yes, with the clarifiers I added today.
Q. You didn't add those clarifiers at the time when you were giving your sworn testimony, true?
A. I did not, no, you are correct.
Q. As a surgeon any time you perform a prolapse surgery, re-operation is a potential risk going into the surgery, correct?
A. That is correct, yes.
Q. And just like you've never guaranteed a patient that a surgery will be complication-free, you've never guaranteed a patient that a surgery necessarily will be effective, correct?
A. Effective as far as treating the symptoms and the anatomical occurrence, I agree with you, yes.
Q. There can be re-operation because of a failure of the prolapse surgery in doing its intended job of fixing the prolapsing problem, correct?
A. That is a risk, yes.
Q. And that's inherent to all prolapse surgeries, correct?

Page 271

A. I don't know of any procedure that is 100% perfect.
Q. There could also be a need for re-operation to -- because a complication has occurred, that necessitates some surgical intervention, correct?
A. Well, again, re-operation can occur, but, again, we have to look at what type of complication it is, how severe it is and can we fix it, but, yes, in a general sense, I agree with you.
Q. And that's inherent to all prolapse repair surgeries, correct?
A. Yes, as I mentioned with all those different qualifiers on there.
Q. You testified this morning about the term mesh exposure; do you recall?
A. Yes.
Q. And you indicated that sometimes the terminology in this area can get -- get confusing because folks use different terms to describe different things?
A. That is correct.
Q. And so whenever you're reviewing any document that talks about complications for mesh surgery, you want to make sure you understand whether

Page 272

the author -- what the author means by a mesh exposure versus mesh erosion, et cetera?
A. That is correct, including the term palpable.
Q. Mesh exposure is a well known risk of any surgery involving mesh, correct?
A. That is true.
Q. Whether the mesh is placed transvaginally or transabdominally, correct?
A. Correct. Again, there is going to be differences in frequency and severity, but, yes.
Q. And so when we're talking about mesh exposure we're talking about when the implanted mesh becomes visible or palpable?
A. In the vagina, correct, not in the bladder or another organ, that's different.
Q. Correct.
And that's called a mesh erosion, right?
A. It should be called that but there will be different terms, that's why it gets confusing for everybody.
Q. So that goes back to how we started this part of our discussion, the terms exposure and erosion sometimes are used interchangeably, but, in your view,

Page 273

there's a clear distinction between them?
A. Correct. You would have to look, when going through medical records, of what the doctor is actually really describing, what they actually saw.
Q. The amount of mesh exposed can be small, correct?
A. It can be, yes.
Q. Mesh exposure actually can be asymptomatic, right?
A. It can be, yes.
Q. When we say "asymptomatic," that means the patient is not experiencing any symptoms from the mesh exposure, correct?
A. That is correct, yes.
Q. When dealing with a mesh exposure the physician can try conservative measures to treat it, right?
A. That is one of the options, yes.
Q. And you certainly advocate conservative methods to treat a mesh exposure, correct?
A. It depends on the severity of the mesh exposure. If it's large, highly symptomatic, then, no. If it's small, asymptomatic, then, yes, as initial treatment.

Page 274

Q. Okay. I appreciate the clarification but just so it's clear, a doctor should consider, in the first instance, whether conservative treatment of a mesh exposure is warranted or whether something more invasive would be appropriate; is that fair to say?
A. That is correct, yes.
Q. Now, with regard to the Prolift®, you agree that approximately 50% of mesh exposures can be treated conservatively?
A. That is, I'd say, old data. If you look at Abbott, et.al., no, they disagree with that, but of those 50% treated conservatively, 50% of those went on to surgery. So the old data, yes, but not the new data.
MR. ISMAIL: Move to strike as nonresponsive.
BY MR. ISMAIL:
Q. If you have your November 15 --
A. 2012, yeah, because that's old.
Q. All right. Well, let me make sure we're clear.
A. Sure.
Q. At the time you gave your sworn testimony in this case you agreed that approximately 50% of mesh

Page 275

exposures can be treated conservatively, true?
MR. SPECTER: Counsel -- pardon me, counsel. I object. When you say "in this case" are you talking about the Hammons case or the transvaginal mesh litigation generally?
MR. ISMAIL: I will rephrase.
MR. SPECTER: Thank you.
BY MR. ISMAIL:
Q. At the time of your November 2012 deposition did you agree, Doctor, that approximately 50% of mesh exposures can be treated conservatively?
A. Yes, I agree with you specifically in 2012, but that's what I'm saying, new data has come out to say that I was incorrect at that time.
MR. ISMAIL: Move to strike as nonresponsive and hearsay everything after "yes."
BY MR. ISMAIL:
Q. The conservative ways of treating a mesh exposure with Prolift® would include just watching and observing the patient to see how she is doing?
A. It has to be a case by case situation.
Q. We've described that conservative treatment of a mesh exposure is sometimes available for

Page 276

a physician and patient, correct?
A. Correct.
Q. And I'm trying to define for the jury what that means when we say "conservative treatment," okay?
A. Okay.
Q. When we say conservative treatment of a mesh exposure, what we're saying is the physician and patient can do nothing but observation to see if the problem improves, correct?
A. That is a treatment option based upon a case by case situation. You have to evaluate all the variables.
Q. And sometimes a conservative treatment option would include use of a topical estrogen cream, correct?
A. That is one of the options, yes.
Q. Less conservative treatment would include excising the exposed mesh, correct?
A. That is correct.
Q. The -- if a -- withdrawn.
Sometimes an excision of exposed mesh can be done in a ten or 15 minute procedure, correct?
A. I can't speak to that. I have not done that.

Page 277

Q. You're aware, Doctor, that some exposed meshes that have gone on to excision can be done in a ten or 15 minute procedure?
A. I don't doubt that it can be done. The question is how effective it is.
Q. Now, this other term that you used, erosion, that was a term that you used with Mr. Slater this morning, correct?
A. That is correct.
Q. And you've defined a mesh erosion to mean when the mesh enters an adjacent organ, correct?
A. Correct, that would be the current terminology.
Q. And that's different than a vaginal exposure of mesh, correct?
A. That is correct, yes, but we have to be careful on who is doing the defining on medical records and things, but, yeah.
Q. Mesh erosion is a well-known risk of any mesh surgery using -- withdrawn.
Mesh erosion is a well-known risk of any mesh surgery, correct?
A. Yeah, but, again, it's going to depend upon which -- you are talking anti-incontinence

Page 278

procedure, prolapse, transabdominal, robotic. There is going to be different risks, severity of the risk of frequency, but, yes, I agree with you.
Q. You mentioned urinary dysfunction this morning in some of your answers to Mr. Slater; do you recall that?
A. Yes, I do.
Q. Urinary dysfunction can be a complication of numerous prolapse surgeries other than with a Prolift®, correct?
A. Again, as I've mentioned, severity, frequency, ability to treat it is going to be different, but it can occur.
Q. In fact, a woman can have voiding dysfunction just from a prolapse in her bladder, correct?
A. That can occur. It's relatively rare, but, yes, it can occur.
MR. ISMAIL: Mr. Slater, during the course of my examination we have sought clarification for the agreement that you say exists regarding payments to witnesses and the feedback that we've gotten -- that I've gotten is that my line of question is perfectly appropriate.

Page 279

MR. SLATER: Who did you speak to? You want to do this on the record?
MR. ISMAIL: Do I want to -- say what now?
MR. SLATER: Do you want to have this conversation on the record?
MR. ISMAIL: I'm telling you that I'm --
MR. SLATER: Who did you talk to?
MR. ISMAIL: We've been doing it by e-mail.
MR. SLATER: With who?
MR. ISMAIL: With the -- I think you called them national folks.
MR. SLATER: No, the national folks weren't in the room when it was made so --
MR. ISMAIL: Well, who -- okay, then perhaps.
MR. SLATER: It was during the deposition of Dr. Weber, the Tucker Ellis lawyers.
MR. ISMAIL: That what?
MR. SLATER: Look, I don't know what they're telling you so --
MR. ISMAIL: Wait a minute.
MR. SLATER: That was what was agreed and look at what they questioned Dr. Weber on, look

Page 280

at the questioning in the other depositions.
MR. ISMAIL: Wait. So you are saying that in our examination of Dr. Weber we agreed not to ask Dr. Weber --
MR. SLATER: Total amount she was paid outside the case, yes. She was only asked about what she was paid in this case.
MR. ISMAIL: And the agreement was inn exchange for what?
MR. SLATER: We would do the same with your experts.
MR. ISMAIL: But did you ask our experts about how much they were paid.
MR. SLATER: I didn't.
Yeah, in this case.
MR. ISMAIL: No, no, in other cases.
MR. TOMASELLI: Ms. Baldwin.
MR. SLATER: Well, I don't know what to tell you about that. Someone should have objected, but, you know, I can just tell you that --
MR. ISMAIL: Okay. So --
MR. SLATER: I don't know why you are shaking your head. This is the agreement. If

Page 281

she asked a question like that, maybe someone in the room could have said to her, hey, did you forget about the deal? And then she -- if she forgot she would have said okay, but I'm not going to change, okay.
Dr. Elliott didn't prepare to talk about total amounts he was paid and that's not what we're going to get into today. That was the agreement in this litigation. In the conversations I was in and with the experts I'm handling, that's how it's been done. If Ms. Baldwin went beyond because she forgot, someone on your side should have been awake and said, hey, we have an agreement, and I'm sure she would have said, oh, I forgot.
MR. ISMAIL: Or that's not the agreement.
MR. SLATER: I think that it clearly was. Did you look at Dr. Weber's transcript?
MR. ISMAIL: I actually have had a chance to read Dr. Weber's transcript.
MR. SLATER: Did you see what she was asked about?
MR. ISMAIL: I know what she was asked about. Whether Dr. Weber was asked or not does

not make it an agreement.
MR. SLATER: Was it placed on the record, on the transcript or was it just agreed with me and Mr. Moriarity and he's not telling you what we talked about? I mean, you think he didn't ask her about what she's been paid in total because he didn't feel like it?
MR. ISMAIL: So I'm just --
MR. SLATER: I know for a fact we made this agreement.
MR. ISMAIL: Okay.
MR. SLATER: So I'm not going to change my position because when I make a deal with somebody, I abide by it and I expect them too also and not send two new lawyers in to pretend they didn't know about it.
MR. ISMAIL: Okay. We have -- Mr. Moriarity is one of the lawyers with whom we checked.
MR. SLATER: He is the one I reached the deal with so I will be happy to speak to him directly.
MR. ISMAIL: Terrific. So my reference to --

MR. SLATER: Want to take a break and put him on the telephone?
MR. ISMAIL: Jesus, can I actually finish my statement?
MR. SLATER: I don't know, can you?
MR. ISMAIL: You keep interrupting me.
MR. SLATER: Sorry.
MR. ISMAIL: So our understanding of what you describe as a deal regarding expert payments and bias is different. Your colleagues in this litigation have not acted as if there is an agreement to that issue. You have asked and your team has asked those questions so we don't think your standing on some blanket objection to covering this with Dr. Elliott is appropriate and to the extent you are correct and some time down the line the Court agrees with you, then that won't get played, but we're all here on a Saturday to accommodate Dr. Elliott's schedule --
MR. SLATER: We're not doing it.
MR. ISMAIL: -- and the appropriate thing to do is to let him answer the question so that we don't have to reconvene testimony of

Dr. Elliott to get what would be bias information because you don't want to do it now, and if you're right, then it doesn't get played to the jury so you are not prejudiced.
MR. SLATER: We're not doing it. In fact, if you talk to national counsel in the MDL you will find that is the agreement throughout the national litigation on both sides.
Have you spoken to them?
MR. ISMAIL: Who is the national counsel in the MDL?
MR. SLATER: Butler Snow.
MR. ISMAIL: Yeah, we've checked with them too.
MR. SLATER: And there's -- in the MDL people are not limiting it to the amount you were paid in that case?
Judge Goodman ruled that when a witness testifies in these trials it's not to be asked about.
MR. ISMAIL: I understand, but the rules in Pennsylvania are different.
MR. SPECTER: Actually, counsel, the rules in Pennsylvania are informed by Maughan versus

Hahnemann, which I suggest you read.
MR. ISMAIL: I did check the rules on whether bias can be -- and whether a witness has been -- has received a significant amount of income testifying on behalf of a certain side, that information is relevant and goes to the jury.
So I'm offering these observations and inviting you to do the sensible thing here and let the witness answer and we can fuss later what gets played to the jury. If we're right, it gets played; if you're right, it doesn't get played.
MR. SLATER: We abide by our agreements, nor do we fabricate different agreements.
MR. ISMAIL: Okay.
MR. SLATER: I once heard someone say that.
MR. ISMAIL: So for the purposes of preserving my record, you're going to instruct Dr. Elliott to refuse to answer any questions about the amount of money he has been paid, other than the time relating to Ms. Hammons, correct?

Page 286

MR. SLATER: Exactly, because that's the agreement we have in this litigation.
MR. ISMAIL: All right. And so no matter how I phrase the question as to the amount of money that Dr. Elliott has been paid by the plaintiffs to testify against Ethicon in particular or other manufacturers, you are going to instruct him not to answer, correct?
MR. SLATER: If you ask him beyond Hammons, he's not going to answer.
MR. ISMAIL: When did he begin working on Hammons, so I know how to phrase the question?
MR. SLATER: I have no idea. Why don't you ask him?
MR. ISMAIL: Well, I don't think he knows either.
As of what date are you going to let him answer the question?
MR. SLATER: Why don't you ask him "how much money have you been paid in this case to your knowledge," and he will do his best to answer the question.
MR. SPECTER: You are talking about the Hammons case, Adam?

Page 287

MR. SLATER: Yeah, in the Hammons case.
MR. ISMAIL: I suspect we're going on -- never mind. Okay. We can go back on the record.
THE VIDEOGRAPHER: Never off.
MR. ISMAIL: We have been on the record this whole time?
THE VIDEOGRAPHER: Yes.
MR. ISMAIL: Excellent. Glad all that was on the record.
BY MR. ISMAIL:
Q. Okay. Now we can go back with the questioning, Doctor.
Among the specific risks that are well known with any pelvic floor surgery is the risk of dyspareunia following the surgery, correct?
A. Again, as I've mentioned, the severity, frequency and ability to treat is going to be different between the procedures, but there is a known risk with each procedure.
Q. During your fellowship you were aware that there was a risk of dyspareunia with prolapse surgeries you were being trained on, correct?
A. Again, as I mentioned, severity and

Page 288

frequency and ability to treat is going to be different between each procedure.
Q. So the answer to that is yes?
A. Well, again, I have to -- I can't just give a yes or no because it's dependent upon each specific procedure. Sacrospinous ligament fixation is different than uterosacral, it's different than anterior colporrhaphy and posterior colporrhaphy.
Q. So let's focus on the colporrhaphy procedure. Those are the native tissue surgeries that -- some of the older surgeries that were used to treat a prolapse, correct?
A. Correct.
Q. You were aware -- withdrawn.
You acknowledge that women with -- who have anterior colporrhaphy can suffer from pain with sexual intercourse after they've had the surgery, correct?
A. Again, with the issue of the severity, frequency and ability to treat it, yes.
Q. During your residency you were aware that there was a potential risk of painful sexual intercourse with colporrhaphy surgeries, correct?
A. I don't know. We're going back a long time there. I didn't learn much in residency on

Page 289

prolapse, that's why I did a fellowship.
Q. All right.
A. So I can't speak with accuracy of what I knew then. Fellowship is a different story.
Q. Let me rephrase my question so -- to make it easier for you.
During your medical training you were aware that there was a potential risk of dyspareunia, painful intercourse with colporrhaphy surgeries, true?
A. Again, I was aware of that issue occurring, but, again, the severity, frequency and ability to treat it is going to be different, but, yes.
Q. When it comes to posterior colporrhaphy the risk of painful sexual intercourse is actually higher than with the anterior repair, correct?
A. You can have papers saying both ways as far as higher and lower, depending upon are you doing a spot repair, are you doing a standard plication, are you using -- so, again, if you compare anterior versus posterior, posterior is going to have a potentially higher risk.
Q. Now, there are many factors that can lead to dyspareunia, correct?
A. Multifactorial is a correct answer, yes.

Page 290

Q. There are many different things that have to be and should be considered when evaluating a woman for dyspareunia, correct?
A. Multiple factors should be considered, yes, that's true.
Q. We talked earlier about the fact that women can have dyspareunia from a prolapse itself, correct?
A. That can happen. It's going to be a different type of dyspareunia but dyspareunia, again, it's a generic term. We're talking if they have a major vault prolapse, they are going to have a different level of discomfort than a sacrospinous fixation or more specific prolapse.
Q. Vaginal atrophy can lead to dyspareunia, correct?
A. Yeah, and usually it's treatable or reducible.
Q. One of the -- and just so we explain to the jury what we mean by vaginal atrophy, one of the things that can occur as a result of menopause is that the woman doesn't make as much estrogen following menopause, correct?
A. Correct.

Page 291

Q. And the decline or decrease in estrogen can lead to vaginal atrophy, correct?
A. Correct.
Q. And vaginal atrophy is something that is associated with menopause, correct?
A. Correct.
Q. And vaginal atrophy is a condition that women have that can progress or get worse as women age, correct?
A. If left untreated, yes.
Q. A vaginal hysterectomy carries the risk of dyspareunia, correct?
A. Yeah. Again, it depends upon the condition being treated. If it's a uterine prolapse, dyspareunia goes -- or is reduced. If it's for some other reason, it could be increased. So, again, we have to look at the specifics.
Q. I just want to make sure you have my question in mind because I'm not sure -- it seemed like you are answering a different question.
The question is, Doctor, a vaginal hysterectomy carries the risk of dyspareunia, true?
A. Yeah, I was being -- I was being more specific as the cause, the etiology of the prolapse.

Page 292

If you just took a generic hysterectomy, can dyspareunia be associated with that? To some extent the answer to that is yes.
Q. Now, let me ask it this way: You would agree that there's a background rate of women who have dyspareunia who have never had any prolapse surgery, correct?
A. That is correct, there is a given percentage that probably increases with age, but, again, we don't know the severity of that and ability to treat it.
Q. The question of whether dyspareunia is associated with prolapse surgery, is something that has been evaluated in randomized controlled clinical trials, correct?
A. Off the top of my head I can't think of the study that has looked at that, but, yeah, I mean, that is a very -- or it should be a very common thing to look at.
Q. You are aware, Doctor, for your work in this litigation that randomized controlled clinical trials have considered whether patients who are surgically -- had prolapse surgically repaired develop dyspareunia, correct?

Page 293

MR. SLATER: Objection.
THE WITNESS: Correct, I would want to look at those specific studies because you have to look at how they are framed, but there are studies out there. I think Lowman, et.al. perhaps is the name. There's going to be others.
BY MR. ISMAIL:
Q. I'm not referring to a specific article now, Doctor, I'm just asking whether you are aware, as part of your work in this case, that randomized controlled clinical trials, some of them, have looked at whether a patient who had a surgical repair of prolapse developed dyspareunia?
MR. SLATER: Objection to this, vague types of questioning. Subject to tie up, you can answer it.
THE WITNESS: You know, looking at the totality of studies out there, yeah, there are studies out there which dyspareunia is a component what they look at. If you are looking at one specifically on dyspareunia and long term, those are going to be fewer.
BY MR. ISMAIL:

Page 294

Q. You're aware that there are randomized controlled clinical studies that have compared the development of dyspareunia following surgery with a group of patients who have had a Prolift® and a group of patients who had native tissue repair?
A. Those studies have been done, yes.
Q. And what those studies allow you to do is see whether -- which group of patients developed dyspareunia and at what rates, correct?
A. Yes and no. During that study period, yes, but it doesn't say anything beyond that.
Q. Then let me rephrase.
One of the things that randomized controlled clinical studies can do in this context that we've been discussing is see, for example, whether during the study period more patients who had the native tissue surgery developed dyspareunia compared to the Prolift®, correct?
A. Yes, as you phrased it there, during the study period, I agree with you.
Q. And you are familiar that those kinds of studies have been done comparing Prolift® to native tissue surgery, true?
A. There have been several studies out there

Page 295

along those lines, yeah.
Q. Certain randomized controlled clinical studies have also assessed whether patients reported an improvement in sexual function following prolapse surgery, correct?
A. Again, I'd want to see the specific study we're referring to.
Q. I'm just asking about your awareness of the body of scientific information when you came to testify today.
A. I'm aware of many studies looking at many things, but each study has to be analyzed very specifically.
Q. I'm just asking generally, Doctor, whether you're aware whether there are randomized controlled clinical studies that have examined whether women have reported improvements in sexual function following prolapse surgery?
A. Yeah, there are studies out there that looked at sexual function following surgery, whether they improve or are worsened.
Q. And you're aware, Doctor, that certain women report improvement in sexual function following surgery with a Prolift®, right?

Page 296

A. Yeah. Again, we have -- I need to see specifics, but in a very general sense that has been reported during that study period. I can't speak to afterwards though.
Q. You earlier, Doctor, read some portion of -- withdrawn.
You made some -- withdrawn.
As you come here today having considered the information that you've described for us earlier with respect to the Prolift® or the Gynemesh® you have not seen any study that has shown a dyspareunia rate of 60% in women using the Prolift®, true?
A. 60%? I mean, I'm not going to be --
Q. That's the number you used earlier in your testimony which is why I asked.
MR. SLATER: Objection, mischaracterization and foundation.
THE WITNESS: Yeah, I'd have to see what I said. I don't know what we're -- it's been a long day so I don't recall those specifics. I'd have to see what I said.
BY MR. ISMAIL:
Q. Then let's clarify.
As you sit here now, Doctor, you are not trying

Page 297

to suggest to the jury that there are studies that report a 60% dyspareunia rate with Prolift®, are you?
A. I'm not prepared -- without looking at the literature, I can't say one way or the other it was 60%, no.
Q. I want to make -- I think we had a double negative in there.
You agree, as you sit here today, you are not suggesting to the jury that there are studies reporting a 60% dyspareunia rate with Prolift®, true?
A. Yeah, right now as I sit here, I can't recall that study.
Q. And, Doctor, you're aware of randomized controlled clinical studies that have shown during the study period that Prolift® has no higher rate of dyspareunia compared to native tissue surgery, true?
A. Well, again --
MR. SLATER: Objection.
MR. SPECTER: Pardon me, counsel.
MR. SLATER: Objection.
MR. SPECTER: Let me just interpose an objection if I may, counsel. You have several times now made reference to literature without showing it to the witness, without asking if

it's authoritative. That can't be evaluated by the witness or by opposing counsel so I object to all those questions, including that past one, for that reason.

MR. SLATER: That was part of my objection previously too, when I asked about tie up because I don't think it's appropriate.

MR. ISMAIL: Well, first of all, I'm not sure who is objecting and who isn't anymore but --

MR. SPECTER: We both were.

MR. ISMAIL: Clearly.

BY MR. ISMAIL:

Q. Doctor, here is my question and if you tell me you don't know, then you tell me you don't know.

Are you aware of randomized controlled clinical trials that have shown that for the study period Prolift® was not associated with an increased risk of dyspareunia?

MR. SLATER: Objection, same reasons previously stated and --

THE WITNESS: Again --

MR. SLATER: And one second -- and we're

going to move to strike all these questions at the appropriate time because they're inappropriate.

THE WITNESS: Again, this is very frustrating for me because I need to see these papers and whenever I bring up a paper's name, you move to strike it and so now when you are asking, I ask for the paper and so I can't see it. So I need to look at the paper, the quality of the paper and let's discuss each paper.

MR. ISMAIL: Move to strike as nonresponsive.

BY MR. ISMAIL:

Q. You can't answer my question, Doctor?

A. I just did. I can't -- you are correct, as you are phrasing it, I can't. I want to see those papers.

Q. All right. Do you have your testimony that you gave on March 4, 2015, sir?

A. Yes, I do.

Q. Page 539, Line 24.

A. 539.

Q. Yes, sir.

A. 539, Line 4. I'm there.

Q. Sorry, Line 23.

A. Oh, I'm sorry. 23, yes.

Q. "Question: And as reported in the studies, am I correct that there has been no difference or no showing among the studies we've talked about to suggest that Prolift® has a higher rate of dyspareunia than the native tissue?

Answer: I agree with -- as you stated that question, I agree with the caveat as I mentioned before."

And then you were asked to answer that question yes or no.

And at Line 13 you said, I agree with you as stated, yes.

Is that your sworn testimony?

A. That's what I state there. I don't know what studies we're referring to.

Q. So you can put that aside, Doctor, and let me ask it this way: without reference to the testimony, do you now recall, Doctor, that there are randomized controlled clinical trials that have demonstrated for the study period that Prolift® is not associated with an increased rate of dyspareunia compared to native

tissue surgeries?

A. Again, I was very specific with that testimony and being consistent, you know, there are a lot of clarifiers you have on there. During the study period, randomized control, I would want to see those studies. We can talk about each one individually, but that's what I stated on March 4. I stand by that.

Q. My question is different, Doctor. I'm not asking with regard to the testimony. I'm asking about your recollection now.

A. Okay.

Q. My ques -- my purpose was to refresh your recollection, okay?

A. Okay.

Q. So here's my question: Do you recall, as you sit here today, that there are randomized controlled clinical studies that have shown for the study period that Prolift® is not associated with an increased risk of dyspareunia compared to native tissues?

MR. SLATER: Objection, it's the same objection. And I just want to say one other thing, I've looked at the testimony now, your foundation is -- it's a mischaracterization and

Page 302

lack of foundation for this line of questioning about RCTs versus the testimony you read. You should look at the line of questioning. It's not based on an RCT, but go ahead.

MR. ISMAIL: So I will restate my question so you have it in mind.

THE WITNESS: Well, no --

MR. ISMAIL: No, I will and to address Mr. Slater, I have the option of refreshing the witness' recollection without showing the testimony and that's what this question is, okay?

MR. SLATER: Without showing the testimony?

MR. ISMAIL: Yes, on the screen to the jury, that's what refreshing recollection is. You don't publish it to the jury. So which I --

MR. SLATER: No, I'm just telling you that what you did was, in my opinion, inappropriate and a mischaracterization of what actually was going on there.

MR. ISMAIL: I got your question -- I got your objection, so here's my question.

Page 303

BY MR. ISMAIL:

Q. Doctor, without reference to the testimony, let me start over, okay. You can put it aside.

As you sit here today, sir, do you have a recollection that there are randomized controlled clinical studies that have shown for the study period that Prolift® is not associated with an increased increase of dyspareunia compared to native tissue surgeries?

A. Okay. With my hands being somewhat tied, because I can't look at these studies, I do have a recollection of there being studies, in the short term, that can show it being equivocal or not statistically different between Prolift® and the native repairs.

Q. Okay. And when you say "not statistically different" in your last answer, just so that the jury is clear, researchers perform a statistical significance test often when doing clinical research, correct?

MR. SLATER: Objection, mischaracterization, lack of foundation.

THE WITNESS: Correct.

BY MR. ISMAIL:

Page 304

Q. And when we talk about statistical significance in clinical research, that is a process by which you say is the observation we're looking at potentially by chance or is it -- you know, fairly represent what the outcomes with the treatment being offered, correct?

A. Correct, if it's by chance or if it's a real finding.

Q. And your last answer was -- withdrawn. One second. Let's break for one minute.

THE VIDEOGRAPHER: Off the record. 2:52 and we are off the record.

(Brief recess.)

THE VIDEOGRAPHER: The time is 3:16 and we are back on the record.

BY MR. SLATER:

Q. Dr. Elliott, you were just asked some questions about whether or not one can attribute complications to a Prolift® where a woman has issues after a Prolift® surgery, do you remember you were asked about that by defense counsel a while back?

A. Yes.

Q. If a patient as a mesh erosion, are you able to say, just knowing that, that the Prolift® is a

Page 305

factor in that complication?

MR. ISMAIL: Objection, incomplete hypothetical.

THE WITNESS: Yes.

BY MR. SLATER:

Q. And why is that?

A. Without mesh there would be no erosion.

Q. If a patient has mesh contraction and that is causing symptoms, are you able to say that the mesh and the Prolift® itself is a part of a factor in causing that complication?

A. Yes, without mesh there's no contraction.

Q. During the questioning by defense counsel you were asked several questions about the risks of the Prolift® through the vagina versus the other types of surgery, for example, abdominal sacrocolpopexy, and I think you were trying to draw some distinctions. I'd like to give you an opportunity now to explain what the distinctions are in terms of the various complications or issues that can arise from these different surgeries?

A. Okay. Just in general?

Q. Sure.

MR. ISMAIL: Objection to the narrative.

Page 306

THE WITNESS: You have to look at the -- what is done during the two procedures, Number one, abdominal versus going through the vagina, so the risk of contamination of the mesh is going to be different. You have to look at the shape of the mesh.

There are no arms for sacrocolpopexy, not going through any muscles, so you can't have that contraction pulling on muscles.

You can get the mesh to lay flat because, again, it's not being pulled like we talked about earlier with the mesh arms.

The volume of mesh is significantly different, like when we showed -- when I picked up the mesh. In general, those are the specifics.

BY MR. SLATER:

Q. You were asked by defense counsel if there are some patients who have had some improvements in their quality of life and you acknowledged, yes, some patients have had improvement with the Prolift®.

Do you remember that?

A. Yes.

Q. Have there been patients who have had

Page 307

complications with the Prolift®?

A. Oh, yes, yeah.

Q. Have there been patients who have had severe life-changing complications with the Prolift®?

A. Yeah.

MR. ISMAIL: Objection, lack of foundation, repeating direct.

THE WITNESS: Devastating complications.

BY MR. SLATER:

Q. You were asked multiple questions about suture surgeries and suture repairs.

Do suture surgeries have mesh-related risks?

A. No.

Q. You were asked a question a few minutes ago and I think counsel said something about older procedures that were used to treat prolapse and he mentioned colporrhaphy I think a few minutes ago.

Is colporrhaphy done today?

A. It's the most common procedure done today.

Q. So it's not an older procedure in the sense that it's something people used to do but don't do anymore; is that fair?

A. No, it's considered what we say is the traditional surgery, been done for many years and will

Page 308

continue to be done.

Q. Is anybody performing Prolifts® today?

MR. ISMAIL: Objection, 403, subsequent remedial measure.

THE WITNESS: No.

BY MR. SLATER:

Q. You were asked about studies, RCTs in particular that study dyspareunia.

Are you familiar with the fact that in the Altman RCT they found a 7% de novo dyspareunia rate with the Prolift® and only 2% with colporrhaphy?

MR. ISMAIL: Objection, hearsay, leading.

THE WITNESS: That's what they state in the report, yes.

BY MR. SLATER:

Q. You were asked if there were some women who report improvement in sexual function after the Prolift®?

A. Correct.

Q. Are there some women who report quite different results with their sexual function after the Prolift®?

A. Yes.

Q. For example?

Page 309

A. Worsening, devastated or gone, that's what I see in my clinic.

MR. ISMAIL: Objection, move to strike.

BY MR. SLATER:

Q. Doctor, do you have handy the transcript that counsel asked you about from March 4, 2015?

A. Yes, I have it right here.

Q. What I'm going to do is go back and look at it a little bit and let's see what you were actually asked about at that time. And if you look at Page 536, Line 9, the article that was identified --

A. I'm sorry. I'm sorry, let me just get there.

Q. Sure. Page 436, Line 9, the article that was identified is the Lowman article?

A. That is correct.

Q. You know that study, you are familiar with that?

A. Yes.

MR. ISMAIL: Objection, hearsay.

MR. SLATER: I'm sorry, didn't you question him about it, sir?

MR. ISMAIL: No, I didn't question him about 536. I was his own transcript and asking

him a question about it, and said here's a statement of him.
BY MR. SLATER:
Q. If you read forward, and you can scan forward from Page 536 where it was identified and if you get to this testimony you were actually asked about by defense counsel, Page 539, Page 540, that's all asking about the Lowman article, correct?
A. Yes, that is all the Lowman article.
Q. All right. Well, we happen to have that here --
MR. ISMAIL: Objection, hearsay.
MR. SLATER: And here it is, PLT302. Here you go, counsel.
MR. ISMAIL: Thank you.
BY MR. SLATER:
Q. And I'm just going to try to do this fairly quickly. This is the published article where they in the results say there was a de novo rate of dyspareunia of 16.7%.
You see that?
MR. ISMAIL: Objection, hearsay.
THE WITNESS: Correct, that's what they state.

BY MR. SLATER:
Q. Now, let's look at Exhibit PLT1096, which is the abstract that predated the published article. And in the abstract look at the conclusion --
MR. ISMAIL: Sorry. Objection, hearsay and this is not a material that Dr. Elliott disclosed. It's beyond the scope of his disclosure so it's improper.
MR. SLATER: Okay. Well, you brought it up.
MR. ISMAIL: No, I didn't actually, but go ahead. The objection is hearsay and improper disclosure of material.
BY MR. SLATER:
Q. Doctor, the conclusion to the abstract by Lowman about whether the Prolift® causes dyspareunia, just read for me the first sentence, please --
MR. ISMAIL: Objection, hearsay.
MR. SLATER: -- of the conclusion.
MR. ISMAIL: Improper disclosure.
THE WITNESS: The abstract which was presented at the --
BY MR. SLATER:
Q. I'm not -- Doctor, I'm talking about the

abstract I just handed to you.
A. Yeah, no, and I can say it was presented at the GYN surgeons meeting in 2008. Just so we're clear what I'm reading here, under conclusion, "The Prolift® procedure may be associated with a high (24%) de novo dyspareunia rate..."
Q. So when they presented it originally they said 24%, a high rate, and then when they published they went down to 16.7%?
MR. ISMAIL: Objection, leading, improper disclosure, hearsay.
THE WITNESS: That is correct.
BY MR. SLATER:
Q. And in the article if you turn to page e5?
A. Okay, I'm there.
Q. And in the center column, if you just read through it, they assess dyspareunia by two different methods, by a validated questionnaire versus a chart review.
MR. ISMAIL: Objection.
BY MR. SLATER:
Q. Do you see that?
MR. ISMAIL: I'm sorry. Objection, hearsay.

THE WITNESS: Yes, and a telephone interview.
BY MR. SLATER:
Q. And, ultimately, if you read through this they say they ultimately chose the chart review, which gave them the 16.7% rate instead of the validated questionnaires that they reported at 24%, didn't they?
MR. ISMAIL: Objection, leading and hearsay.
THE WITNESS: That's what they state in there, yes.
BY MR. SLATER:
Q. These validated questionnaires, these are validated through professional societies and academics and people who know a lot in this field; aren't they?
MR. ISMAIL: Objection, leading, hearsay.
THE WITNESS: That is correct, yes.
BY MR. SLATER:
Q. Okay. Now, you were asked a bunch of questions by counsel about the use of polypropylene to treat pelvic conditions, you remember he asked you about that, it's been used in a lot of products by different ways?
A. Correct.

Page 314

Q. And he asked you about Bard Marlex; do you remember that?
A. Correct.
Q. Are you familiar with the Bard Avaulta?
A. Oh, yes.
MR. ISMAIL: Objection, beyond the scope. I didn't ask him anything about Marlex.
MR. SLATER: You mentioned it.
MR. ISMAIL: No, I didn't. He did. He misunderstood my question.
THE WITNESS: No, I did not misunderstand. I understood it, but I did bring it up.
BY MR. SLATER:
Q. Remember you were asked by counsel about Marlex and that that was one of the materials used to treat patients?
MR. ISMAIL: Objection, actually misstates the record, beyond the scope.
THE WITNESS: I remember the discussion.
BY MR. SLATER:
Q. You were asked about the use of mesh transvaginally?
A. Correct.
Q. All right. And one of the ways that's

Page 315

done -- was done was by the Bard Avaulta, right?
MR. ISMAIL: Object, leading.
THE WITNESS: Correct.
BY MR. SLATER:
Q. And I've given you now the MSDS, the Material Safety Data Sheet, for the Marlex material in the Bard Avaulta and on the -- and you've seen this before, right?
A. Yes, I have.
Q. Marked as Plaintiff's Trial Exhibit P2402 and if you look right on the front page -- let me start again.
If you look on the front page of this Exhibit P2402, what does it say? There is a medical application caution, what does that say?
MR. ISMAIL: Objection, hearsay, beyond the scope, not disclosed in this case by the witness.
BY MR. SLATER:
Q. What does that say?
A. It says "Medical Application Caution: Do not use this Phillips Sumika Polypropylene Company material in medical application involving permanent implantation in the human body or permanent contact

Page 316

with internal body fluids or tissues."
Q. And then what does it say in the next --
MR. ISMAIL: Objection --
BY MR. SLATER:
Q. -- paragraph?
MR. ISMAIL: I'm sorry. Objection, 403, hearsay, beyond the scope.
MR. SLATER: Sure.
BY MR. SLATER:
Q. Does it basically say that, again, don't use this polypropylene material in the human body for medical applications?
MR. ISMAIL: Same objections and now leading.
THE WITNESS: Yes, but it goes on saying "involving brief or temporary implantation in the human body."
BY MR. SLATER:
Q. Okay. And that's -- this is the polypropylene used in one of those mesh devices used transvaginally that counsel asked you about, correct?
MR. ISMAIL: Objection, leading, hearsay, 403, beyond the scope.
THE WITNESS: It's one of the meshes used

Page 317

in one of the products, yes.
BY MR. SLATER:
Q. Okay. Now, you were asked by counsel about conservative treatment of exposure erosion, remember that, counsel asked you a bunch of questions?
A. Yes, I do.
Q. Do you have handy or can you get handy PLT1095, it's the article by Heesakkers and Withagen. I actually have another copy of it here, if it will save time.
MR. ISMAIL: Which one?
MR. SLATER: It's the one I gave you at the start of the day today.
MR. ISMAIL: Thank you.
BY MR. SLATER:
Q. And what I want to do -- this is the article by that urologist that you said you knew from SUFU.
A. Yeah, John Heesakkers. Not from SUFU, from European Urology Association.
Q. Ah, sorry. And if we look now at Page 1399 of this article which you already testified about --
MR. ISMAIL: Objection, hearsay, 403. I

Page 318

didn't ask him about the article, you did.
So beyond the scope, 403, hearsay and this is the article that, as we pointed out before, was not disclosed by the witness before today.
BY MR. SLATER:
Q. Okay. Doctor, during the cross-examination counsel asked you about the efficacy of using conservative treatments to treat mesh erosions; do you remember that?
A. Correct.
Q. And if we look at Page 1399 of this article, and you look at the left-hand column, first full paragraph it says, "Mesh-related complications were unsuccessfully treated conservatively with estrogen cream, antibiotics and/or physiotherapy prior to mesh excision in 63% of patients."
Is that significant --
MR. ISMAIL: Objection, hearsay --
BY MR. SLATER:
Q. -- to you?
MR. ISMAIL: Sorry. Objection, hearsay, 403, improper disclosure.
MR. SLATER: You have a standing objection for hearsay, counsel.

Page 319

MR. ISMAIL: Okay. Thank you. I'm actually adding to the objection, but thank you. Did I get them all?
403, improper disclosure, beyond the scope. Thank you.
THE WITNESS: Yes, it's quite significant.
BY MR. SLATER:
Q. Why is that?
MR. ISMAIL: Same objections.
THE WITNESS: Traditionally, and if you look at what I answered in 2012 deposition, is that 50% of these mesh extrusions can be treated conservatively and that's it.
Researchers like this Dutch group, along with Abbott, are now saying that 50% of those which are treated conservatively ultimately go on to surgery, and this one actually says 63%, so it's actually a higher percent than Abbott, et.al.
BY MR. SLATER:
Q. Okay. Now, you were asked a bunch of questions by counsel about RCTs and how many studies there are of the Prolift®; do you remember that questioning?

Page 320

A. Yes, I do.
MR. SPECTER: RCT.
BY MR. SLATER:
Q. Randomized controlled trials, right?
A. Correct.
Q. That's when they take a few different procedures and they compare them, basically.
A. A two-armed study, yes.
Q. Okay. And are you -- well, let me hand you this. This is going to be Exhibit 2503.
And this is a letter from the FDA to Mr. Brian Kanerviko, a worldwide director of regulatory at Ethicon.
You see this?
A. Yes, I do.
Q. Okay. And you are familiar -- are you familiar or not with the interaction between Ethicon and the FDA regarding the 522 studies?
A. Yes, I've read those.
Q. Okay. And what I'd like to do is to cut to the chase, let's turn to Page 4 of this letter.
MR. ISMAIL: Counsel, if you wouldn't mind giving me a second when you hand me an exhibit to see what it is.

Page 321

I object to this exhibit as beyond the scope, 403, beyond the time period at issue in this case and potentially subject to a stipulation that you proposed.
BY MR. SLATER:
Q. In Paragraph 10 of this letter to the FDA I just want to read a little bit and then I'm going to ask you a few questions. It says, "For GYNECARE PROLIFT® Pelvic Floor Repair Systems, you provided 2 published articles with the clinical data collected under two randomized controlled trials to satisfy the 522 orders. However, these studies do not address several questions in the 522 order."
Do you see that?
A. Yes I do.
MR. ISMAIL: Same objections and also hearsay.
BY MR. SLATER:
Q. And just simply, the 522 orders were where the FDA wrote and told Ethicon you need to do some very high level studies in order to prove these are -- this is a safe product, the Prolift®?
MR. ISMAIL: Same objections and now with leading.

Page 322

THE WITNESS: Right, it's a response saying there's an application and here's where we have concerns.
BY MR. SLATER:
Q. And the FDA talks about which two RCTs they're talking about and it's Withagen and Altman, correct?
MR. ISMAIL: Objection, leading, hearsay. 403.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Let me ask the question differently.
THE COURT REPORTER: One at a time, please.
BY MR. SLATER:
Q. Rephrase.
Which of the two articles, if you look in the body of these two bullet points that the FDA is describing that Ethicon had submitted to try to satisfy the 522?
MR. ISMAIL: Just let me make my objections noted which didn't get last time, because it was talked over.
Hearsay, 403, beyond the scope and

Page 323

improper disclosure. Thank you.
THE WITNESS: Withagen, et.al. and Altman, et.al.
BY MR. SLATER:
Q. And according to this did the FDA accept those articles as satisfying the FDA's concerns and need for a 522 order, study?
MR. ISMAIL: Objection, hearsay, 403, beyond the scope and improper subject for expert testimony.
BY MR. SLATER:
Q. What did they say at the bottom of that section? It says "Based on these limitations ..."
MR. ISMAIL: Same objections.
THE WITNESS: To answer your question initially, no, they did not say it was satisfying. And then, "Based on these limitations, the publications provided are not adequate to satisfy the 522 order."
BY MR. SLATER:
Q. And now I'll hand you exhibit we marked as P2452 and this is a letter from the FDA to Brian Kanerviko, worldwide director regulatory in Ethicon, July 9, 2012.

Page 324

And you've seen this before?
A. Yes.
Q. And it says in the letter that the FDA had completed its review of Ethicon's response to the 522 order requesting that the study be suspended, and they say, "This request is based on the plan to discontinue manufacture and marketing of the device in the United States within 120 days of the date of your letter. We agree to your request and will place the 522 order on hold until September 7, 2012 with the following conditions:"
Is that what the letter says?
MR. ISMAIL: Objection, hearsay, 403, beyond the scope, subsequent remedial measure, improper subject of expert testimony.
THE WITNESS: That's what it states.
BY MR. SLATER:
Q. And the first condition there is "Cease marketing by September 7, 2012."
Is that what it says?
MR. ISMAIL: Please note the same objections.
THE WITNESS: That what it states.
BY MR. SLATER:

Page 325

Q. And then just below the conditions, it says, "FDA reminds you that you are obligated, under Section 522 of the act, to complete a postmarket surveillance study of your device to address the issues cited in FDA's letter dated January 3, 2012. Accordingly, you must submit us new study plan to your PS study informing" -- meaning post market surveillance study -- "informing FDA if commercial distribution of your device begins."
Is that what the letter says?
MR. ISMAIL: Please note the same objections.
THE WITNESS: That's what it states, yes.
BY MR. SLATER:
Q. And is it consistent with your understanding that after Ethicon said they weren't going to do the 522 studies and withdraw the products, that they actually withdrew the Prolift® from the market and no longer sell it?
MR. ISMAIL: Objection, leading, 403, beyond the scope, subsequent remedial measure, lack of foundation.
THE WITNESS: Yes, it was --
MR. ISMAIL: Sorry. Improper subject for

Page 326

expert testimony. Sorry, Doctor.
THE WITNESS: It was pulled from the market, yes.
MR. ISMAIL: Move to strike as nonresponsive.
MR. SLATER: No other questions.
BY MR. ISMAIL:
Q. Doctor, just briefly.
You were asked -- earlier I showed you your sworn testimony from 2012 and you indicated that 50% of mesh exposures can be treated conservatively, correct?
A. Correct.
Q. What was the date of the article that counsel showed you just now in response to that testimony, Exhibit 1095?
A. Looks like it was published in 2011.
Q. In the event counsel's question regarding the Altman study on redirect -- redirect is allowed, I have some follow-up on that provisionally.
You were asked to -- he provided you what he characterized as the data on dyspareunia between Prolift® surgery and the native tissue surgery in that study, correct?
A. Correct.

Page 327

Q. And he gave you some data points where numerically the rate of dyspareunia was higher with Prolift®.
Do you recall that was the information he gave you?
A. That is correct.
Q. Do you recall from your own memory, sir, that the dyspareunia rate between Prolift® and native tissue surgery in that Altman study was not statistically significant?
A. In the Altman study?
Q. Yes.
A. I don't have the Altman study in front of me. If you are telling me it's statistically equal, I have no reason to doubt you.
Q. Okay. So let me ask it this way: When you were answering Mr. Slater's questions when he gave you data points regarding that study, you did not recall, from your own recollection, whether the data he was giving you was at all accurate, correct?
MR. SLATER: Objection. By the way, I just want to preserve my objections on this line of questioning.
THE WITNESS: With -- actually, I'm sorry,

Page 328

could you repeat your question.
BY MR. ISMAIL:
Q. Just so everything is clear as to where this is coming from, just now, a few minutes ago Mr. Slater represented to you certain data from a study known as Altman, correct?
A. Correct.
Q. He gave you the numbers from that study in his question, but would I be fair to assume you didn't recall them yourself?
A. No, I -- no, you are correct, I don't recall them, but the Altman study has major issues that --
Q. I didn't bring it up.
MR. SLATER: Don't interrupt him in the middle of the answer, please. Let him finish.
BY MR. ISMAIL:
Q. Doctor, I just want to make sure --
MR. SLATER: No, no, hang on, hang on, he was talking. Let him finish. He is going to finish.
MR. ISMAIL: Then I will move to strike and we try again.
MR. SLATER: That's fine but you should

Page 329

let him finish his answer.
MR. ISMAIL: Okay, okay, calm down.
THE WITNESS: Point well-taken.
But as I mentioned earlier, the Altman studies have major ethical issues, which I questioned the data. But to answer your question, I do not recall off the top of my head those numbers.
MR. ISMAIL: Move to strike.
BY MR. ISMAIL:
Q. Doctor, quite simply, when Mr. Slater represented to you what the data were from the Altman study, you did not, and still as you sit here now, do not know whether that data he gave you was the true reported data from that study, correct?
A. I don't recall those specific numbers out of the hundreds of studies I read, no.
Q. That's fine, and I'm not -- withdrawn.
And as you sit here today you can't recall whether the rate of dyspareunia comparing Prolift® to native tissue repair in the Altman study, if there was a numerical difference, whether that was statistically significant or not, true?
A. As I recall it was not statistically

different.
Q. Okay. And so the proper interpretation of a study where there are comparison between one surgical treatment and another surgical treatment, if it's not statistically significant, the proper interpretation of that is you would say the study does not show a difference for that outcome, correct?
A. Yeah, the proper way to state it is there was a percentage difference but not a statistical difference.
Q. Right.
And when you say there is not a statistical difference, earlier when we were talking about statistical significance, that's a way researchers can assess whether the observed difference is real or due to chance, correct?
A. That is correct.
Q. And if there's no statistically significant difference, one would conclude that there is -- that any observed difference between the two groups of patients in this study is potentially due to chance, correct?
A. Correct, during the frame of -- time frame of that study, that is correct.

Q. And in the Altman study, as you've just confirmed, where there's no statistically significant difference in the outcome of dyspareunia, the proper interpretation of that study is that the Altman study does not establish -- withdrawn.
The proper interpretation of the Altman study is that there was no statistical difference shown in the risk of dyspareunia comparing Prolift® to native tissue surgery, true?
MR. SLATER: Just for the record, I've clearly stated an objection to this whole line of questioning.
THE WITNESS: To answer your question, you are correct as it is stated in the document, with the reservations I've had as far as the -- is it a true study.
BY MR. ISMAIL:
Q. Okay. But as to the data that Mr. Slater gave you, it wasn't -- I didn't give you that data, he gave you that data, right?
A. Correct.
Q. And if you were going to interpret the data he gave you, where there was an absence of statistical significance, you would conclude the Altman

study does not show an increased risk of dyspareunia comparing Prolift® to native tissue surgery, true?
MR. SLATER: Same objection.
THE WITNESS: As I review any study, not just this, not just for this litigation, you have to look at the percentage, the true numbers and then the statistical significance and you cannot -- if they're statistically equal, then you have to state that statistically they were equal.
BY MR. ISMAIL:
Q. And that was true with respect to the risk of dyspareunia in the Altman study that Mr. Slater gave you just now, correct?
A. That is correct, yes.
MR. ISMAIL: Thank you. No further questions.
MR. SLATER: Just for the record, make it very clear, the questioning on Altman was conditional in case any of the vague questioning on cross-examination regarding studies, without establishing them as being authoritative, would be permitted in any way.
I have no other questions.

THE VIDEOGRAPHER: The time is 3:41 and this concludes the videotape deposition of Dr. Daniel Elliott.
(Witness excused.)
(Mr. Slater leaves the deposition room.)
MR. ISMAIL: We have requested the stenographic record note that the deposition remains open due to the instructions not to answer. Mr. Slater was advised but was outside the deposition room.
_ _ _

Page 334

CERTIFICATION

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR
CSR #XI01497 Notary Public

Page 335

ERRATA

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Page 336

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
DANIEL S. ELLIOTT, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.

My commission expires:_____

_____
Notary Public